A multicentre, randomised trial comparing combination gemcitabine/carboplatin and hydroxychloroquine versus carboplatin/etoposide therapy alone in small cell lung cancer (SCLC)

PATIENT INFORMATION SHEET

IRAS Number: 198726
We are inviting you to take part in a research trial called STUDY 15

We would like to invite you to take part in a trial. Before you decide whether or not to take part, one of your doctor’s team will go through this patient information sheet with you and answer any questions you may have so that you fully understand why we are running the trial and what it would involve for you.

Please take the time to read the information carefully and talk to others about the trial if you wish. Ask us if there is anything you don’t understand or if you would like more information and take your time to decide whether or not you wish to take part.

You are free to decide if you want to take part in this research trial. If you choose not to take part, this will not affect the care you get from your own doctors in any way.

You can decide to stop taking part in the trial at any time without giving a reason.

Thank you for reading this information. If you decide to take part, we will ask you to sign a form to give your consent for the trial.

Important things that you need to know

We are carrying out this research to discover whether the addition of the drug hydroxychloroquine increases the effectiveness of combination chemotherapy in patients diagnosed with small cell lung cancer (SCLC).

Half of the patients entered onto the trial will receive hydroxychloroquine and combination chemotherapy, whilst the other half will receive combination chemotherapy alone.

All patients will receive between four to six cycles of chemotherapy and will be followed up for a maximum of 36 months after the last trial chemotherapy is administered.

Patients in the hydroxychloroquine and chemotherapy group will start taking hydroxychloroquine on the first day of the first cycle of chemotherapy, for a maximum of 30 months.

All patients in the trial will be receiving chemotherapy as part of their treatment and therefore are likely to experience a range of associated side effects. The patients who will be receiving hydroxychloroquine may experience additional side effects. Detailed information is provided in section 8.
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1. What is the purpose of the trial?
You have a type of lung cancer called small cell lung cancer (SCLC). Your doctor will have explained that chemotherapy is considered the most appropriate treatment for you. Chemotherapy for SCLC usually includes two chemotherapy drugs given together (where one of the two drugs is platinum based e.g. carboplatin or cisplatin). The combination often used is carboplatin and etoposide.
Recent research has suggested that the addition of a drug called hydroxychloroquine (HCQ) may make some anticancer drugs more effective. We hope that HCQ will make cancer cells more sensitive to chemotherapy, thereby making treatment more effective.
There are two different treatment options on the trial:
- Group 1 - etoposide and carboplatin
- Group 2 - gemcitabine and carboplatin with HCQ
Research has shown HCQ cannot be taken with etoposide. However, another chemotherapy drug, gemcitabine, when given with carboplatin works just as effectively and can be safely given alongside HCQ. The aim of this trial is to see whether HCQ will slow the growth of your cancer.

2. Why have I been invited?
You have been invited to participate because you have been diagnosed with stage IV SCLC and your doctor considers you suitable for the trial.
112 patients will be invited to take part in the trial.

3. Do I have to take part?
No. It is up to you to decide whether or not to take part in the trial. We will describe what would be involved and go through this patient information sheet with you, which is yours to take away so that you have the opportunity to read it carefully and discuss the trial with others if you wish.
If you decide to take part, we will ask you to sign a consent form. You are free to withdraw at any time, without giving a reason. If you decide not to take part, or later to withdraw, this will not affect the standard of care you receive.

4. What will happen to me if I take part?
All patients willing to take part in the trial will be asked to sign an informed consent form.
Prior to beginning treatment you will have some investigations to check that it is safe for you to receive treatment. Some of these will be done as part of normal care but some will be extra tests that are required for the trial. Sometimes some of the tests need to be repeated if they are outside the required timescale for the trial. These tests and assessments may include:
- A CT scan
- A head CT scan (if your doctor feels this is necessary)
- A physical examination to include standard reading chart and eye assessments
- Height and weight measured
- Electrocardiogram (ECG)
- Blood tests
- Kidney function tests (may include use of EDTA)
- Liver function tests
- Pregnancy test (if you are a woman of childbearing potential)
- Quality of life questionnaires
- Medical history
- Adverse events
- Other medications you are taking
- Vital signs (blood pressure, heart rate etc.)
- Details about your age, gender and smoking history
- We would also like to take additional blood samples for extra research (see section ‘Exploratory/Translational Research’).

You will be assessed to ensure that you meet all the criteria for the trial. These assessments will provide us with baseline information which will be used (alongside other information we collect throughout the trial) to assess whether the trial is successful.

If it is confirmed that you are able to take part in the trial, you will be placed in one of the 2 groups: chemotherapy and HCQ OR chemotherapy only (no HCQ) by a computer. This is a process called randomisation. This means that neither you nor your doctor, will be able to decide which treatment you will have. Trials are often randomised because if the researchers or doctors were to decide who should get which treatment, they might be influenced by what they know about their patients. Having randomisation allows us to be sure that results are reliable and that a fair comparison between the treatment groups can be carried out.

All patients in both groups of the trial will receive chemotherapy in three weekly (21 day) cycles for a maximum of 6 cycles. Whilst receiving chemotherapy all patients will need to visit the hospital to receive G-CSF treatment, in addition to taking 7 days’ worth of antibiotics each cycle (see figure 1). G-CSF and antibiotics are used to minimise risk of infection whilst undergoing chemotherapy.

During the trial you will be assessed regularly to ensure that it is safe for you to continue on the current treatment. You will be seen at every chemotherapy visit (day 1 of each cycle for all patients and an extra day 8 visit for patients in the chemotherapy and HCQ group – see figure 1). All patients will be seen monthly for the first year after completing chemotherapy and thereafter every two months until the trial is completed. The tests and assessments during treatment and follow up may include:

- CT scans
- Chest x-rays
- Physical examinations to include standard reading charts and eye assessments
- Blood tests
- Kidney function tests (may include use of EDTA)
- Liver function tests
- Quality of life questionnaires
- Vital signs (blood pressure, heart rate etc.)
- Weight
- Pregnancy test (if you are a woman of childbearing potential)
- Adverse events
- Other medications you are taking
Chemotherapy only group
If assigned to this group, you will receive the chemotherapy treatment of carboplatin and etoposide.

You will receive both of the chemotherapy drugs through a drip in your hand or arm (Intravenous - IV) on day 1 of each cycle. Your doctor will then choose whether to give you an oral dose of etoposide on days 2 and 3, which you can take home, or, an IV dose which you will need to go to the hospital for. If you take oral doses of etoposide, you should take a dose in the morning and evening, on an empty stomach. If you forget or are sick after taking a dose it is important to take only your regular dose at the next scheduled time. You should not double the next dose to try to make up for the one you missed. You will need to record any missed/vomited doses in the notes section of the patient diary you will be given.

Chemotherapy and HCQ group
If assigned to this group, you will receive chemotherapy treatment of carboplatin and gemcitabine with oral tablets of HCQ. You will start taking HCQ on day 1 of the first cycle and will continue to take HCQ every day for a maximum of 30 months. If your cancer starts to grow or spread, or your doctor is concerned at the side-effects you are experiencing then you might reduce the dose of HCQ you are taking or stop taking HCQ altogether before the 30 months is completed.

You will receive the two chemotherapy drugs through a drip in your hand or arm (Intravenous - IV) on day 1 of each cycle and a further dose of IV gemcitabine on day 8. In addition, you will take an oral dose of HCQ every day, at home with food. HCQ doses should always be taken before chemotherapy. HCQ doses should be taken at least 8 hours apart (ideally 10-12 hours apart).
If you miss a dose of HCQ, you should take it as soon as you can unless it is within eight hours of the next dose e.g. if you take your evening dose at 10pm, it would be ok to take the morning dose up until 2pm if you had forgotten it that morning. Do not double the next dose to make up for the one you missed. If you vomit the dose, take your next dose as usual and do not take another dose to make up for it. Record any missed/vomited doses in the notes section of the patient diary you will be given.

**Following completion of treatment**

Following completion of IV chemotherapy, patients in both groups will have monthly assessments (see section 4 - ‘What will happen to me if I take part?’ for more information) for the first year and then every other month thereafter. These assessments will continue for a maximum of 36 months after the last administration of trial chemotherapy. They may be stopped before this if your cancer shows signs of progressing (growing back or spreading).

**Exploratory/translational research**

We would like to carry out extra research to help researchers to understand SCLC better and improve outcomes for future patients.

Research samples will be prepared from the specimen taken when your cancer was diagnosed. We need to access the pathology report. Please be assured that the hospital will remove your name from this before they send it to the researchers so we will be unable to see any directly identifiable information. We would also like to take a blood sample from you when we start you in the study. This blood sample will be approximately the equivalent of 5-6 teaspoons of blood (which is 20mls).

Your doctor will talk through the extra research with you, and you will be asked to provide consent.

**5. What will I have to do?**

If you agree to participate in this trial you will need to attend the hospital and have the tests and treatments carried out as described above. It is essential that you follow the assessment and drug schedule as closely as possible.

To help you with this, you will be given a patient diary, which you need to complete and bring to all hospital visits. You will also need to bring any remaining HCQ/etoposide, including packaging (even if empty).

You will be given a patient card to carry with you while you are on treatment. This will give details of the trial treatment and contact details for your hospital. The card should be shown to any other doctors who may treat you during your treatment.

**6. What are the alternatives for treatment?**

Patients diagnosed with SCLC are usually treated with a combination of two chemotherapy drugs (where one of the two drugs is platinum based e.g. carboplatin or cisplatin). The combination often used is carboplatin and etoposide. Half the patients who enter onto the trial will receive this chemotherapy regimen.

Patients randomised to the other group will receive HCQ and a combination of gemcitabine and carboplatin. This
chemotherapy regimen has been shown to be equally as effective as carboplatin and etoposide.

If you choose not to take part in this trial, your rights to receive the best medical care from your doctor will not be affected. Your doctor will talk to you about your treatment options.

7. What are the possible benefits and disadvantages/risks of taking part?

We hope that the information we get from this study will help us to improve our knowledge of treating Small Cell Lung Cancer which we hope will benefit patients in the future.

For patients in treatment group 1 (which is standard treatment for this cancer) there are no additional benefits of taking part in this study beyond those of the standard treatment for your cancer. These would be the same if you did not take part in this study.

Patients in treatment group 2 will be receiving a combination treatment that we think may be more effective compared to the standard, however we do not know this for sure which is the reason behind this research – to help us understand.

The main disadvantages of taking part are mostly associated with the side effects of the chemotherapy you will receive as part of the trial, however these would be similar to those received as your standard treatment even if not in the trial.

Patients who will receive the additional HCQ may experience side effects relating to the drug. A full list of possible side effects can be found in section 8.

Before participating you should consider if taking part in the trial will affect any private medical insurance you have and seek advice from your provider if necessary.

8. What are the side effects of any treatment received when taking part?

As all patients in the trial will be receiving carboplatin as part of their chemotherapy treatment, the ‘General Treatment Side Effects’ section applies to all patients. The specific drug sections will outline additional side effects you may experience. Side effects specific to the other treatments will not be listed again if already listed in the ‘General Treatment Side Effects’ section.

General Treatment Side Effects

Lowered resistance to infection

Treatment can reduce white blood cells made by the bone marrow, making you more prone to infection. You may have headaches, aching muscles, a cough, sore throat, pain passing urine or feel cold and shivery. If your temperature goes up, or you suddenly feel unwell, even with a normal temperature, contact your trial doctor or the hospital straight away. Most hospitals consider a temperature above 38°C (100.5°F) to be high, although some hospitals use a lower or higher temperature. The doctors and nurses will advise you when you need to contact the hospital.

Anaemia (low number of red blood cells)

While having treatment, you may become anaemic. This may make you feel tired and breathless. Let your doctor or nurse know if you have such problems.
Bruising or bleeding
Treatment can reduce the production of platelets, which help the blood to clot. Let your trial doctor know if you have any unexplained bruising or bleeding, such as nosebleeds, blood spots or rashes on the skin, and bleeding gums.

Nausea and vomiting
If you feel sick it may begin soon after the treatment is given and last for a few days. You may feel sick but it is unusual to actually vomit. Your trial doctor will prescribe you anti-sickness (anti-emetic) drugs to prevent or greatly reduce nausea and vomiting. If you are sick and this continues, tell your doctor. They can prescribe anti-sickness drugs that may be more effective.

Hair loss
This usually starts after the first or second cycle of chemotherapy. Hair is usually lost completely but may just thin. You may also have thinning and loss of eyelashes, eyebrows and other body hair. Hair loss is temporary and your hair will re-grow once the treatment is finished.

Kidneys
Usually this does not cause any symptoms, and the effect on the kidneys is mild, but if the effect is severe the kidneys can be permanently damaged unless the treatment is stopped. Your kidneys will be checked by a blood test before each cycle of treatment. Fluid will be given into the vein before and after treatment to keep your kidneys working normally. You may be asked to drink extra fluid before and after treatment; it is important to do this.

Liver
Treatment may cause changes in the way your liver works, though your liver will return to normal when the treatment is finished. In severe cases it is serious and therefore your trial doctor will monitor this carefully. Samples of your blood will be taken from time to time to check your liver is working properly.

Hearing
Your hearing can be affected. You may get ringing in your ears (tinnitus) and lose the ability to hear some high-pitched sounds. Tinnitus usually gets better after treatment. Some hearing changes can be permanent. Tell your trial doctor if you notice any changes in your hearing.

Numb or tingling hands or feet
Peripheral neuropathy is the numb or tingling sensations you may experience and is caused by the effect of the treatment on the nerves. You may find it hard to fasten buttons or do other fiddly tasks. Tell your doctor if you have these symptoms. The symptoms usually improve slowly after treatment finishes, but in some people they may never go away.

Allergic Reactions
Skin rashes (including severe blistering and peeling) can occur so your doctor will regularly ask about any rashes. Fever and an increased tendency to itch has also been associated with treatment. Please tell your doctor if you experience any of these symptoms. Treatment can be given to ease discomfort from the side effects.

Lungs
It is very common for patients to experience difficulty in breathing when receiving treatment. It is usually mild and
will improve rapidly without treatment. You may also suffer from a cough and/or stuffy nose. If the symptoms worsen it is important that you contact your trial doctor immediately to seek advice.

**Heart**
Irregular heartbeat, heart failure, blood clots and stroke have all been reported.

**Sore Mouth**
Your mouth may become sore, or you may notice small ulcers during the treatment. Drinking plenty of fluids and cleaning your teeth regularly and gently with a soft toothbrush can help reduce the risk of this happening. You may also experience a change in normal taste. Tell your nurse or doctor if you have any of these problems as they can prescribe special mouthwashes and medicine to prevent or clear any mouth infection.

**Vision**
You may experience a temporary worsening of eyesight or changes to your vision. Rarely, cases of temporary sight loss have been reported. Please talk to your trial doctor if you are concerned.

**Loss of appetite**
If you experience loss of appetite it is important to tell your doctor.

**Nervous System Disorders**
You may experience a group of symptoms such as headache, altered mental functioning, seizures and abnormal vision (from blurriness to vision loss). These are symptoms of reversible posterior leukoencephalopathy syndrome, a rare neurological disorder.

**Hydroxychloroquine (HCQ)**

**Visual impairment**
Your trial doctor will make sure that regular assessments of your vision are done throughout the trial and your treatment dose can be reduced or stopped if your vision worsens. Any changes in night/central vision including blurring of vision should be reported to your nurse/clinician immediately. The risk to your vision is low but increases the longer HCQ is taken for.

**Hypoglycaemia (low blood sugar levels)**
Your blood sugars will be monitored regularly by your trial doctor. If you experience any of the following; palpitations, tremours, hunger or sweating, please report this to your nurse/clinician. Your doctor may feel the need to reduce the dose or stop your treatment if your blood sugar is affected.

**Diarrhoea and Abdominal Pain**
If you experience diarrhoea or abdominal pain it is important to tell your doctor. Your doctor can reduce the dose of your HCQ or stop treatment.

**Skin**
Severe itching of the skin has been reported. Very rarely, cases of erythema multiforme (rash), Stevens-Johnson syndrome (layers of the skin separating), photosensitivity, Dress Syndrome (severe unusual reaction to treatment), AGEP (red swollen skin) and isolated cases of exfoliative dermatitis (redness and peeling of skin) have been reported. Report any severe skin reactions to your trial doctor. Skin conditions are usually resolved after stopping treatment.
Psychiatric disorders
If you experience increased changes in mood and emotion it is important you tell your trial doctor.

Build-up of fluid
You may experience areas of swelling of the skin and tissue just under the skin. The swelling may occur in the face, tongue, larynx, abdomen, or arms and legs. Report any severe changes to your trial doctor.

Porphyria
Porphyria is a group of diseases in which substances called porphyrins build up, negatively affecting the skin or nervous system. Symptoms of an attack include abdominal pain, chest pain, vomiting, confusion, constipation, fever, high blood pressure, and high heart rate. Report any severe changes to your trial doctor.

Psychosis
Psychosis is a change in the normal conditions of the mind, involving a change in perception of reality. Depending on its severity, you may experience unusual or strange behaviours. There is also a chance that you will experience difficulty with social interaction and carrying out daily life activities. Please speak to your doctor if you are concerned.

Nervous System Disorders
You may experience headaches, insomnia, or tiredness. Also stroke, seizures and confusion have been reported but are rare. Contact your trial doctor if you experience any of these side effects.

Skin
Although rare, cases of toxic epidermal necrolysis and Stevens-Johnson syndrome have been reported (both conditions involve the two layers that make up skin, separating). Report any severe skin effects.

Gemcitabine Site Effects

Loss of appetite
You may lose your appetite during your treatment. Try to eat small meals regularly. Don’t worry if you don’t eat much for a day or two. If your appetite doesn’t improve after a few days, let your nurse or dietitian know. They can give you advice on getting more calories and protein in your diet. They may give you food supplements or meal replacement drinks to try.

Build-up of fluid
You may put on weight or your face, ankles and legs may swell because of fluid build-up. Tell your doctor or nurse if this happens. If your ankles and legs swell, it can help to put your legs up on a foot stool or cushion. The swelling will reduce after your treatment ends.

Aching or pain in joints and muscles
You may get pain in your joints and muscles for a few days after chemotherapy. Tell your trial doctor if the pain does not get better.

Diarrhoea and constipation
If you experience diarrhoea or constipation, it is important to tell your trial doctor.

Nervous system disorders
You may experience headaches, insomnia, or tiredness. Also stroke, seizures and confusion have been reported but are rare. Contact your trial doctor if you experience any of these side effects.
reactions to your trial doctor. Itching and sweating are commonly reported. Speak to your trial doctor if symptoms worsen or are of concern.

**Blood in urine**
Seeing blood in your urine is very common but notify your doctor and discuss if you are concerned.

**Blood pressure changes**
You may experience changes in blood pressure after receiving treatment. This can result in you experiencing dizziness or fainting. If you experience these symptoms then contact your trial doctor.

**Shortness of Breath**
This is commonly reported by patients. It is usually mild and passes quickly without treatment. If symptoms persist or worsen please talk to your trial doctor as in rare cases this can be serious.

**Flu like Symptoms**
You make experience a cough or inflammation of the nose potentially leading to runny nose, sneezing or a stuffy nose. If symptoms persist or worsen please talk to your trial doctor.

**Etoposide Side Effects**

**Severe Allergic Reactions**
Such as fever, loss of heat, rapid heartbeat, abnormal contraction of muscles of bronchioles, shortness of breathing, stopping of breathing, low muscles tone and low blood pressure. Contact your trial doctor if you experience any of these side effects

**Tiredness**
Feeling tired and generally unwell is a common side effect. It’s often worse towards the end of treatment and for some weeks after it’s finished. It is important to allow yourself plenty of time to rest.

**Abdominal pain and constipation**
You may experience some abdominal pain and/or constipation. It is important that you talk to your nurse or doctor before you take any over-the-counter laxatives or stool softeners. You may also experience a lack of appetite.

**Second cancer**
Etoposide can increase the risk (≥1 in 100 but <1 in 10) of developing a second cancer in the future (5 to 8 years after treatment), usually leukaemia. However the benefits of having etoposide usually far outweigh this risk. Your trial doctor can talk to you about this and you should raise any concerns that you may have.

**Blood pressure changes**
You may experience changes in blood pressure after receiving IV etoposide. This can result in you experiencing dizziness or fainting. If you experience these symptoms then contact your trial doctor.

**Loss of vision**
Although rare, partial or complete loss of sight has been reported. The loss in sight may be short term (last minute to hours) or long term. If visual loss is experienced you should get in contact with your trial doctor immediately and discuss the symptoms. Your trial doctor will inform you of any changes in treatment or further investigations required.

**Skin**
Although rare, cases of toxic epidermal necrolysis and Stevens-Johnson syndrome have been reported (both conditions involve the two layers that make up skin, separating). Report any severe skin
reactions to your trial doctor. You may also experience pigmentation (change in skin colour) or an increased urge to itch the skin. Skin conditions usually resolved after stopping treatment.

**Inflammation**
You may experience mucositis (inflammation of digestive tract), stomatitis (inflammation of mouth and lips) or oesophagitis (heart burn). If you experience these symptoms then contact your trial doctor.

**9. Ionising Radiation (Medical Exposure) Regulations – IRMER**
Participating in this study means you may receive more CT scans than you would if you were receiving the normal standard of care.

During CT scans you will be exposed to ionising radiation in the form of X-ray scans and radioactive injections with a tracer dye. Ionising radiation can potentially be harmful.

The total amount of radiation from the scans you will have over your time on the study will not normally exceed about 72mSv (milliSievert, which are small units of radiation dose). That total dose equals to roughly 24 years of natural background radiation. Background radiation is the naturally occurring radiation in the environment coming from the earth itself and from cosmic rays from outer space that we are all exposed to every day. For a person with your condition the risk of any harmful effects from the extra diagnostic scans will be very small.

**10. Harm to the unborn child: therapeutic studies**

**For men**
Please share this information with your partner if appropriate:

- It is possible that the trial medicine will affect sperm or semen and therefore you should not father a child and must use a condom or practice abstinence during this trial or for a safety period of six months after treatment.

- If your partner is or could become pregnant you (or your partner – see guidance for women) must use at least 1 highly effective form of contraception during treatment and for 6 months afterwards. Highly effective forms of contraception are vasectomy also called male sterilisation (with appropriate post-vasectomy documentation of the absence of sperm in the ejaculate) or absolute and continuous abstinence.

- If your partner becomes pregnant during the trial, or within 6 months of stopping treatment, you must tell your trial doctor immediately. We would discuss referral for specialist counselling on the possible risks to your partner and your unborn baby.

Due to the possibility of treatment-related infertility the trial doctor or nurse will provide you with information on sperm banking if you wish.

**For women**
Please share this information with your partner if appropriate:

- Due to the effects of carboplatin, etoposide, gemcitabine and
hydroxychloroquine it is possible that they could be present in breast milk. Therefore if you are breast-feeding or pregnant you will not be able to take part in the trial.

- If there is a chance that you could become pregnant, you will be asked to take a pregnancy test before entering the trial to ensure that you are not pregnant.

- If you are of child bearing potential and miss a period during the trial, you will be asked to take a pregnancy test to check whether you are pregnant.

- All samples taken for the pregnancy tests as part of the trial will be destroyed once the results are obtained.

- You must agree to use at least 1 form of highly effective contraception during your treatment. These are hormonal contraceptives, intrauterine devices or systems (also called the hormonal coil), sterilisation where both fallopian tubes have been blocked/cut, a vasectomised male partner or absolute and continuous abstinence. This must continue for the time you are receiving treatment and for 6 months after you finish your treatment.

- If you do become unexpectedly pregnant during the trial, you must inform your trial doctor immediately.

- Due to the possibility of treatment-related infertility the trial doctor or nurse will provide you with information on egg cryo-preservation or sperm banking if you wish.

For all

- We would like to monitor pregnancies occurring during or following study treatment provided consent is given for this. Information will be provided in a separate pregnancy monitoring information sheet and consent will be taken on separate pregnancy monitoring consent form. Information will be given and consent taken when pregnancy occurs.

- This information is important because it helps us to better understand the effect of the trial treatment on pregnancy and the unborn baby.

11. Travel Expenses

Taking part in this study means there may be more hospital visits than would normally be the case if you were not in the study. We will be able pay for reasonable travel expenses to the hospital for these additional visits if requested.

12. What happens when the trial stops?

Once you are on this trial, the doctor will continue to collect information about how well you are and how you are doing.

When the trial is completed the care from your doctor will continue as planned. Your hospital doctor will be able to advise you on treatment at all times during and after the trial.

13. What if there is a problem?

Every care will be taken in the course of this clinical trial. However, in the unlikely event that you are injured by taking part, compensation may be available. If you suspect that the injury is the result of the Sponsor’s (University College London) or
the hospital's negligence then you may be able to claim compensation. After discussing with your clinical trial doctor, please make the claim in writing to Professor Siow Ming Lee who is the Chief Investigator for the clinical trial, based at University College London Hospital. The Chief Investigator will then pass the claim to the Sponsor’s Insurers, via the Sponsor’s office. You may have to bear the costs of the legal action initially and you should consult a lawyer about this.

Participants may also be able to claim compensation for injury caused by participation in this clinical trial without the need to prove negligence on the part of University College London or another party. You should discuss this possibility with your clinical trial doctor in the same way as above.

Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been approached or treated by members of staff or about any side effects (adverse events) you may have experienced due to your participation in the clinical trial, the normal National Health Service complaints mechanisms are available to you. Please ask your clinical trial doctor if you would like more information on this. Details can also be obtained from the Department of Health website: [http://www.dh.gov.uk](http://www.dh.gov.uk).

14. **Will my participation in the trial be kept confidential?**

Yes, all information collected during the trial will be kept strictly confidential.

Details about you, your treatment, any side-effects you have, how the disease responds and how you are during and following trial treatment will be recorded in your medical notes at your hospital.

The trial staff at your hospital will then pass information relevant to your participation in the trial to the Cancer Research UK & University College London Cancer Trials Centre (UCL CTC). This information will include your initials, date of birth and NHS number.

UCL CTC is registered under the UK Data Protection Act 1998 and all information held at UCL CTC will be stored securely for 25 years and handled according to these data protection guidelines. When you join the trial you will be assigned a trial number by UCL CTC. All your trial data at UCL CTC will be identified using only this number and will be entered into the trial database by UCL CTC staff. This number will also be used to link your trial information to any tissue or blood samples collected.

The information collected about you as part of the trial might be looked at by staff from UCL CTC, the sponsor (or representatives of the sponsor), regulatory authorities, laboratories and your NHS Trust/Health Board. This is to ensure that the trial is being carried out properly and that the information collected is correct. These organisations will always keep information about you confidential.

Your name will never be used in any reports about the trial. Where there is a possibility that your data may be sent outside the UK for regulatory or research purposes, UCL CTC will take reasonable steps to ensure the principles of the Data Protection Act are maintained.
Your trial doctor will tell your GP about your participation in the trial.

15. More information about taking part
What if relevant new information becomes available?
Sometimes we get new information about treatments being studied in trials. If this happens, your trial doctor will tell you and discuss with you whether you would like to continue in the trial. If you decide not to carry on, your trial doctor will make arrangements for your care to continue outside the trial. If you decide to continue in the trial, you may be asked to sign an updated consent form.

In some circumstances your trial doctor might consider it best for you to withdraw from the trial. They will explain the reasons and arrange for your care to continue outside the trial.

If the trial is stopped for any other reason, your trial doctor will tell you and arrange your continuing care.

What will happen if I don’t want to carry on with the trial?
You can withdraw from trial treatment at any time but we would like to continue to collect information about you through your doctor so that we know about your progress following trial treatment. We will also need to use the information collected up to your withdrawal. After this/at the time of your withdrawal any stored blood or tissue samples that can be identified as yours will be destroyed if you wish.

What will happen to any samples I give?
An extra blood sample may be taken for research purposes when you are screened for the trial. Where possible, the blood sample will be taken at the same time as a routine blood sample.

The researchers would also be interested in collecting diagnostic tissue from procedures performed at this hospital or any other hospital for this trial and other future cancer research. The diagnostic tissue will be used for this study and may also be used in other ethically approved research, transferred to another tissue bank for use in future research or, if requested, returned to the hospital where it was taken to be used to help make clinical decisions.

Any samples which you provide will be given a unique identifier and so your identity will be anonymous to the laboratories studying the samples. If necessary, for example if you request that your samples are destroyed, it will be possible to trace your samples through the UCL CTC using the coding created by the UCL CTC. Otherwise, your samples will be regarded as a donation and will be used for lung cancer research in the future.

All samples will be stored and analysed at central laboratories. The samples may also be used in future scientific studies in lung cancer, and some of these studies may involve collaborations with scientists from other countries.

At the end of the research or at the time of trial withdrawal if there are any samples left these will bio-banked.
Samples may be transferred and stored in laboratories where commercial research will be carried out. If a commercial product were developed using this research, you will not be eligible to benefit financially from this.

**Will any genetic tests be done?**
Genetic studies will be performed to study the genetic influences on lung cancer and treatment. The results will not affect you directly. No clinical genetic tests will be done for specific known inherited diseases.

**What will happen to the results of the trial?**
The information collected during this trial will be used in analyses and will be published/presented to the scientific community at meetings and in journals. It is expected that the trial results will be published after recruitment on the trial is complete. Your trial doctor will be informed when the results are available and you can ask him/her about the progress of the trial. A printed results summary will be made available on the Cancer Research UK website. No individual patient will be identified in any report or publication.

**Who is organising and funding the research?**
The trial is funded by the London Lung Cancer Group (LLCG).

The trial has been endorsed by Cancer Research UK, is being sponsored by University College London and run by Cancer Research UK & UCL Cancer Trials Centre (UCL CTC), London.

Your doctor will not be paid for including you in the trial.

**Who has reviewed the trial?**
All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect the interests of any patients that may take part. This trial has been reviewed and granted a favourable opinion by the East Midlands - Derby Research Ethics Committee and the Medicines & Healthcare Products Regulatory Agency (MHRA) and has also been approved by the Research and Development department at your hospital and the Cancer Research UK Clinical Trials Advisory and Awards Committee (CTAAC).

**16. Contacts for further information**
If you want further information about the trial, please contact your trial doctor or nurse as below:

**Trial Doctor:**

**Trial Nurse:**
Alternatively if you or your relatives have any questions about this trial you may wish to contact one of the following organisations that are independent of the hospital at which you are being treated:

- **Macmillan Cancer Support** provides practical and financial support and counselling to help people live with cancer. They can be contacted at:
  Tel: 0808 808 00 00 (freephone) - Monday to Friday, 9am to 8pm

- **Cancer Research UK** can provide all aspects of information for people. You can call a cancer information nurse on:
  Tel: 0808 800 4040 (freephone) - Monday to Friday, 9am to 5pm

**Thank You**

Thank you for considering taking part in this trial and for taking the time to read this patient information sheet, which is yours to keep. If you decide to take part in the trial, you will also be given a copy of your signed consent form.

### Glossary

<table>
<thead>
<tr>
<th>Abbrev</th>
<th>Full Name</th>
<th>What it means</th>
</tr>
</thead>
<tbody>
<tr>
<td>CI</td>
<td>Chief Investigator</td>
<td>The doctor with overall responsibility for the trial</td>
</tr>
<tr>
<td>CR UK</td>
<td>Cancer Research UK</td>
<td>A charity supporting the trial</td>
</tr>
<tr>
<td>CTAAC</td>
<td>Clinical Trials Advisory and Awards Committee</td>
<td>A committee within CR UK that reviews and funds cancer clinical trials</td>
</tr>
<tr>
<td>CT scan</td>
<td>Computer Tomography</td>
<td>A CT scan takes a series of x-rays, which build up a three-dimensional picture of the inside of the body. The image produced is very detailed.</td>
</tr>
<tr>
<td>EDTA</td>
<td>Ethylene Diamine Tetra Acetic Acid</td>
<td>An EDTA test is the most accurate method of calculating kidney function. EDTA is the name of the substance that you will receive by injection and contains a small amount of radioactive material, which can be tracked to allow kidney function to be calculated.</td>
</tr>
<tr>
<td>G-CSF</td>
<td>Granulocyte-colony stimulating factor</td>
<td>G-CSF is a growth factor given after chemotherapy that makes the bone marrow produce blood cells, to help fight infection.</td>
</tr>
<tr>
<td>SCLC</td>
<td>Small Cell Lung Cancer</td>
<td>About 12 out of every 100 lung cancers are diagnosed with small cell lung cancer. The type of cancer is usually caused by smoking.</td>
</tr>
<tr>
<td>UCL</td>
<td>University College London</td>
<td>This is the organisation that takes responsibility for the running of the trial, known as the Sponsor.</td>
</tr>
<tr>
<td>UCL CTC</td>
<td>UCL Cancer Trials Centre</td>
<td>The organisation carrying out the day to day work on the trial</td>
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