PAIReD

Phase II study of reduced intensity allogeneic transplantation for refractory Hodgkin lymphoma

Phase II trial involving 47 patients with primary refractory or relapsed refractory Hodgkin's disease, designed to document the toxicity, feasibility and survival following reduced intensity transplantation using the BEAM-Alemtuzumab protocol

STUDY DESIGN

Eligible patients with suitable donor

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Consent & Register

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Central review of PET

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RIC allograft

(BEAM-Campath conditioning)

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Follow up (3 years)

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DLI for mixed chimerism and residual or relapsed disease

SAMPLE SIZE: 47 patients

CHIEF INVESTIGATOR:

Dr Karl Peggs – University College London

PATIENT ELIGIBILITY

- Patients with a confirmed diagnosis of Hodgkin lymphoma
- HLA-compatible sibling or unrelated donor (at least 9/10 match)
- Two subgroups of patients will be included in the study:
  - Primary refractory HL achieving <CR to one or two lines of salvage chemotherapy
  - HL in first relapse achieving <PR to one or two lines of salvage chemotherapy
- Age 16-65 years
- WHO performance status 0-1
- Written informed consent
- No concurrent serious medical condition that would preclude an allograft
- No previous high dose therapy or allograft
- Adequate renal, hepatic, cardiac & pulmonary function
- No pregnant or lactating women
- No previous malignancy in past 5 years (except non-melanoma skin tumours or in situ cervical carcinoma)
- HIV negative

SITE ELIGIBILITY

- Static PET-CT scanner required, this must be approved by PET review group
- MDT including specialists in lymphoma and stem cell transplantation

PRIMARY OBJECTIVES

- 3 year progression free survival

SECONDARY OBJECTIVES

- Donor engraftment rates
- Non-relapse mortality
- Incidence, severity and timing of GvHD
- Response rates
- Relapse rates
- Response to donor lymphocyte infusions
- Overall survival

CENTRAL PET REVIEW

University College Hospital, London are coordinating the PET QA assessment and performing central review of patients' PET scans.

Data CDs for baseline and follow up PET-CT scans are to be sent to UCL CTC to forward to the review team.

BIOLOGICAL SAMPLES AND POST-TRANSPLANT MONITORING

- There is no central pathology review for this trial
- Sites should perform weekly CMV virology for 3-6 months post transplant in CMV seropositive patients or recipients of stem cells from CMV seropositive donors
- Chimerism status should be assessed by STR every 3 months from 3 months post transplant until 2 years

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PAIReD – Haematology Trials Group

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