

A randomised controlled comparison of Campath-Tacrolimus vs IL2R MoAb-Tacrolimus /Mycophenolate as induction-Maintenance immunosuppression in kidney transplantation (protocol SMHREN0501)

Submission date

28/09/2007

Recruitment status

No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date

28/09/2007

Overall study status

Completed

☐ Statistical analysis plan

☒ Results

Last Edited

17/02/2015

Condition category

Urological and Genital Diseases

☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr Adam McLean

Contact details

HHNT Renal Unit
4th Floor Hammersmith House
Hammersmith Hospital
Du Cane Road
London
United Kingdom
W12 0HS
+44 (0)208 383 5152
amclean@hhnt.nhs.uk

Additional identifiers

ClinicalTrials.gov (NCT)

NCT00246129

Protocol serial number

N0016188158

Study information

Scientific Title

A randomised controlled comparison of Campath-Tacrolimus vs IL2R MoAb-Tacrolimus /Mycophenolate as induction-Maintenance immunosuppression in kidney transplantation (protocol SMHREN0501)

Study objectives

To determine which of two well established anti-rejection drug combinations has the best outcome in kidney transplantation.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Primary study design

Interventional

Study design

Randomised controlled open study

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Urological and Genital Diseases: Kidney transplant

Interventions

Randomised controlled open study

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Campath-Tacrolimus

Primary outcome(s)

1. An understanding of the merits of these two anti-rejection treatment combinations.
2. One year survival with a functioning graft

Key secondary outcome(s)

1. Occurrence, severity, and type of infection episodes
2. Initial length of stay in hospital and subsequent admissions
3. Cost over the first year of the two therapies
4. Presence in the blood of cells which might trigger rejection in, or promote tolerance to the graft
5. Early development of scarring in the grafts
6. Graft function
7. Patient survival and graft survival censored for death with function

Completion date

01/12/2008

Eligibility

Key inclusion criteria

Adults undergoing liver donor or deceased donor kidney transplantation

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. Patients who are unable to give written informed consent
2. Simultaneous kidney/pancreas transplant recipients
3. Non-heart beating deceased donor transplant recipients
3. Patients who would not be offered Campath-1H induction under our current protocol (patients with previous malignancy or with previous exposure to cytotoxic or antiproliferative agents)

Date of first enrolment

01/12/2005

Date of final enrolment

01/12/2008

Locations

Countries of recruitment

United Kingdom

England

Study participating centre
Hammersmith Hospital
London
United Kingdom
W12 0HS

Sponsor information

Organisation

Record Provided by the NHSTCT Register - 2007 Update - Department of Health

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Hammersmith Hospital NHS Trust

Funder Name

St Mary's Hospital

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	15/10/2011		Yes	No