ISRCTN73171002 https://doi.org/10.1186/ISRCTN73171002

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

Registration date
28/09/2007

Overall study status
Completed

Last Edited
17/02/2015

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00246129

Secondary identifying numbers
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

Study design
Randomised controlled open study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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

Secondary outcome measures
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

Overall study start date
01/12/2005

Completion date
01/12/2008

Eligibility

Key inclusion criteria
Adults undergoing liver donor or deceased donor kidney transplantation

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
120

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
England

United Kingdom

Study participating centre
Hammersmith Hospital
London
United Kingdom
W12 0HS

Sponsor information

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

Sponsor details
The Department of Health
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL
+44 (0)207 307 2622
dhmail@doh.gsi.org.uk

Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Hammersmith Hospital NHS Trust

Funder Name
St Mary's Hospital

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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