

# 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**

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**Contact details**

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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?
<a href="#">Results article</a>	results	15/10/2011		Yes	No