

A single centre, randomised controlled, open label study of rituximab as induction therapy in kidney transplantation

Submission date 30/03/2005	Recruitment status Stopped	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 10/05/2005	Overall study status Stopped	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 19/09/2017	Condition category Surgery	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

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

2005-001496-35

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

A single centre, randomised controlled, open label study of rituximab as induction therapy in kidney transplantation

Acronym

Rituxicam2005

Study objectives

Primary objective: To evaluate the effect of rituximab compared to daclizumab on the incidence and severity of acute rejection

Secondary objectives:

To evaluate the effect of rituximab on patient and graft survival following transplantation

To evaluate the differences in gene expression patterns in patients immunosuppressed with rituximab compared to daclizumab by microarray analysis

Ethics approval required

Old ethics approval format

Ethics approval(s)

Huntingdon Research Ethics Committee, ref 05/Q0104/144, date 19/12/2005.

Study design

Single centre randomised controlled open label study

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Not Specified

Participant information sheet

Health condition(s) or problem(s) studied

Immunosuppression following renal transplantation

Interventions

Comparison of rituximab with daclizumab as induction immunosuppression following renal transplantation

Added 01/02/2010: The trial was stopped prematurely due to an excess of acute rejection in the study arm.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Rituximab, daclizumab

Primary outcome measure

1. Acute rejection incidence
2. Acute rejection severity - Banff scale
3. Incidence of steroid resistant rejection, defined as the need for ATG therapy

Secondary outcome measures

1. Patient survival
2. Graft survival
3. Graft function estimated glomerular filtration rate (GFR)
4. Incidence of infection culture positive infections
5. Incidence of C4d+ endothelial staining together with infiltrate on renal biopsy
6. Incidence of anti-donor HLA-specific antibody in post transplant sera

Overall study start date

01/04/2006

Completion date

31/03/2014

Reason abandoned (if study stopped)

Objectives no longer viable

Eligibility**Key inclusion criteria**

Patients undergoing renal transplantation

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

120

Key exclusion criteria

Age under 18 years

Date of first enrolment

01/04/2006

Date of final enrolment

31/03/2014

Locations

Countries of recruitment

England

United Kingdom

Study participating centre**Dept of Surgery**

Cambridge

United Kingdom

CB2 2QQ

Sponsor information

Organisation

Cambridge University Hospitals NHS Foundation Trust (UK)

Sponsor details

Addenbrooke's Hospital

Hills Road

Cambridge

England

United Kingdom

CB2 2QQ

Sponsor type

Hospital/treatment centre

ROR

<https://ror.org/04v54gj93>

Funder(s)

Funder type

Industry

Funder Name

Roche Products Limited (UK)

Funder Name

Cambridge Transplant Unit (UK)

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	18/06/2009		Yes	No