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

Submission date 30/03/2005	**Recruitment status** Stopped	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data [_] Record updated in last year
Registration date 10/05/2005	**Overall study status** Stopped	
Last Edited 19/09/2017	**Condition category** Surgery	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Mr Christopher Watson

Contact details
Dept of Surgery
Box 202
Addenbrooke's Hospital
Cambridge
United Kingdom
CB2 2QQ

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
Comparision 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