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A Phase II Randomised Study of the Addition of Methotrexate 0.05 mg/kg 12 hourly for 8 doses to the Current Immunosuppressant Regimen for the Prevention of Liver Allograft Rejection.

Submission date
30/09/2005

Registration date
30/09/2005

Last Edited
13/03/2014

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Other

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N0265006492

Study information

Scientific Title

Study objectives
Two thirds of patients receiving an orthotopic liver allograft suffer acute graft rejection episodes within the first few weeks post transplant despite current immunosuppressant therapy. This deficiency in current therapy necessitates the administration of high dose steroids in these patients, in a smaller proportion is associated with early graft loss and may in other patients be associated with graft loss from the subsequent development of a chronic graft rejection process. The aim of the proposed trial is to assess the safety and efficacy of the addition to current immunosuppressant therapy of 0.05mg/kg methotrexate given 12 hourly for four days from 24 hours post transplant. The rationale for this therapeutic strategy lies in its common application to the prevention of graft versus host disease after allogeneic bone marrow transplantation; the efficacy of methotrexate in treating established rejection episodes in cardiac allografts; the efficacy of methotrexate in preventing organ allograft rejection in experimental animals.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Study type(s)
Not Specified

Health condition(s) or problem(s) studied
Not Applicable: Liver allograf

Interventions
60 consecutive adult patients who have previously consented to participate in the trial will be randomised to one of two treatment groups at the time of liver transplantation. The treatment groups are 'standard' or 'standard / methotrexate' immunosuppressant regimen. The two treatment groups will be assessed for:
1. Adverse effects attributable to their immunosuppressant therapy
2. Incidence and severity of early graft rejection episodes 3. Use of additional immunosuppressant drugs, particularly corticosteroids
4. Incidence of late acute graft rejection episodes and incidence of chronic graft rejection.

Intervention Type
Drug

Phase
Phase II

Drug/device/biological/vaccine name(s)
Methotrexate

Primary outcome(s)
Not provided at time of registration

Key secondary outcome(s))
Not provided at time of registration

Completion date
01/01/2007

Eligibility

Key inclusion criteria
Not provided at time of registration

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Not Specified

Sex
Not Specified

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/01/2004

Date of final enrolment
01/01/2007

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Liver Surgery
Birmingham
United Kingdom
B15 2TH

Sponsor information

Organisation
Department of Health

Funder(s)

Funder type
Government

Funder Name
University Hospital Birmingham NHS Trust (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration