

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	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 30/09/2005	Overall study status Completed	☐ Protocol
Last Edited 13/03/2014	Condition category Other	☐ 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

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Not Specified

Health condition(s) or problem(s) studied

Not Applicable: Liver allograft

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