ISRCTN58758525 https://doi.org/10.1186/ISRCTN58758525

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 [_] Protocol
Registration date 30/09/2005	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 13/03/2014	**Condition category** Other	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof P McMaster

Contact details
Liver Surgery
Queen Elizabeth Hospital
Birmingham
United Kingdom
B15 2TH

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Not Specified

Participant information sheet

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 measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/01/2004

Completion date
01/01/2007

Eligibility

Key inclusion criteria
Not provided at time of registration

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
60

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
England

United Kingdom

Study participating centre
Liver Surgery
Birmingham
United Kingdom
B15 2TH

Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL
+44 (0)20 7307 2622
dhmail@doh.gsi.org.uk

Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Government

Funder Name
University Hospital Birmingham NHS Trust (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