

# 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.

<b>Submission date</b> 30/09/2005	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 30/09/2005	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 13/03/2014	<b>Condition category</b> Other	<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

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## 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 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 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

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### 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