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A pilot study of thalidomide therapy for alcoholic hepatitis

Submission date 30/09/2005	**Recruitment status** Stopped	[X] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 30/09/2005	**Overall study status** Stopped	
Last Edited 24/11/2011	**Condition category** Digestive System	

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
N0265006466

Study information

Scientific Title

Study objectives
Will suppression of tumour necrotising factor alpha (TNF-a) production by the use of thalidomide lead to a reduction in morbidity and/or mortality in alcoholic hepatitis?

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)
Treatment

Health condition(s) or problem(s) studied
Alcoholic hepatitis

Interventions
Patients referred to the Liver Unit for management of acute alcoholic hepatitis will be invited to participate in the trial provided that they fulfill inclusion criteria according to our proposed protocol. They will be given the study medications or placebo for a total of four weeks and will be monitored during and following this period of trial therapy.

Please note, this trial never started due to logistic problems.

Intervention Type
Drug

Phase
Not Applicable

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

Primary outcome(s)
Survival or death, since severe AH carries a mortality of 50% within two months.

Key secondary outcome(s)
1. Onset of complications such as bacterial or fungal sepsis
2. Renal failure
3. Gastrointestinal haemorrhage

Completion date
01/01/2007

Reason abandoned (if study stopped)
Lack of staff/facilities/resources

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
01/01/2006

Date of final enrolment
01/01/2007

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Liver Medicine
Birmingham
United Kingdom
B15 2TH

Sponsor information

Organisation
Department of Health

Funder(s)

Funder type
Government

Funder Name
University Hospital Birmingham NHS Trust (UK) - Internal funding

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration