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STOPAH: Steroids or pentoxifyline for alcoholic hepatitis

Submission date 23/06/2009	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 26/06/2009	**Overall study status** Completed	
Last Edited 17/12/2020	**Condition category** Digestive System	

Plain English summary of protocol

Background and study aims
In the UK the number of deaths caused by liver disease is increasing dramatically, and the leading cause of liver disease is excess alcohol consumption. Alcohol misuse over a long period leads to alcoholic hepatitis, where there is marked inflammation in the liver. The death rate amongst patients with severe alcoholic hepatitis is over 30% within the first month after admission to hospital. Several studies have shown an improvement in survival rates with the use of prednisolone, a corticosteroid drug which suppresses inflammation. However, other studies, many of which have been criticised for their small size or poor quality, found no benefit to steroid use. In many units around the UK prednisolone is now accepted as standard treatment for severe alcoholic hepatitis but this practice is not consistent and a definitive study is therefore required to determine the best treatment option. A second drug, pentoxifylline, has been shown to be effective in patients with severe alcoholic hepatitis. Pentoxifylline has also been shown to reduce resistance to corticosteroids and might therefore act together with prednisolone to reduce death rates in patients with severe alcoholic hepatitis. Unfortunately only one study of pentoxifylline alone and one study of pentoxifylline in combination with prednisolone have been reported and conclusions about the effectiveness of the drug are therefore hard to draw. The aim of this study is to evaluate the effectiveness of prednisolone and pentoxifylline in patients with severe alcoholic hepatitis.

Who can participate?
Patients aged 18 or over with alcoholic hepatitis

What does the study involve?
Participants are randomly allocated into four groups: a group treated with a placebo (dummy drug), a group treated with prednisolone alone, a group on pentoxifylline alone, and a group on both prednisolone and pentoxifylline. We then measure patient survival after 28 days, 3 months and 12 months, and the development of any disease/treatment complications.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
Imperial College London (UK)

When is the study starting and how long is it expected to run for?
December 2009 to November 2013

Who is funding the study?
NIHR Health Technology Assessment Programme - HTA (UK)

Who is the main contact?
Prof Mark Thursz

Contact information

Type(s)
Scientific

Contact name
Prof Mark Thursz

Contact details
Department of Hepatology
Imperial College London
Faculty of Medicine
St Mary's Campus
Norfolk Place
London
United Kingdom
W2 1PG

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
HTA 08/14/44

Study information

Scientific Title
STOPAH: STeroids Or Pentoxifyline for Alcoholic Hepatitis

Acronym
STOPAH

Study objectives

The primary objective of this study is to determine whether pentoxifylline (PTX) or corticosteroids reduce the mortality associated with severe alcoholic hepatitis.

More details can be found at: http://www.nets.nihr.ac.uk/projects/hta/081444
Protocol can be found at: http://www.nets.nihr.ac.uk/__data/assets/pdf_file/0004/81373/PRO-08-14-44.pdf

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Multicentre randomised double-blind factorial (2 x 2) design trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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

Interventions
The planned interventions will be prednisolone (40 mg for 4 weeks) or pentoxifylline (400 mg 3 times a day for 4 weeks):
1. Group A: placebo/placebo
2. Group B: placebo/prednisolone
3. Group C: pentoxifylline/placebo
4. Group D: pentoxifylline/prednisolone

Intervention Type
Drug

Phase
Phase III

Drug/device/biological/vaccine name(s)
Pentoxifyline, prednisolone

Primary outcome measure
Mortality at 28 days

Secondary outcome measures
1. Mortality at 3 and 12 months
2. Outcome relative to Glasgow Alcoholic Hepatitis Score
3. Assessment of biochemical response to treatment
4. Duration of hospitalisation
5. The development of new or recurrent renal failure
6. Development of gastro-intestinal haemorrhage and sepsis
7. Incremental NHS costs and quality of life at 3 and 12 months

Overall study start date
01/12/2009

Completion date
30/11/2013

Eligibility

Key inclusion criteria
1. Clinical alcoholic hepatitis:
1.1. Serum bilirubin greater than 80 µmol/L
1.2. History of excess alcohol (greater than 80 g/day male, greater than 60 g/day female)
2. Less than 4 weeks from admission to hospital
3. Discriminant Function (DF) greater than or equal to 32
4. Informed consent
5. Minimum 18 years old, no upper limit, either sex

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
1200

Total final enrolment
1068

Key exclusion criteria

1. Abstinence of more than 6 weeks prior to randomisation
2. Duration of jaundice greater than 3 months
3. Other causes of liver disease
4. Evidence of current malignancy (except non-melanotic skin cancer)
5. Previous entry into the study, or use of either prednisolone or PTX within 6 months
6. Aspartate aminotransferase (AST) greater than 500 or alanine aminotransferase (ALT) greater than 300
7. Patients with a serum creatinine greater than 500 µmol/L or requiring renal support
8. Patients dependent upon inotropic support
9. Active gastro-intestinal haemorrhage and untreated sepsis

Date of first enrolment
01/12/2009

Date of final enrolment
30/11/2013

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Imperial College London
London
United Kingdom
W2 1PG

Sponsor information

Organisation
Southampton University Hospitals NHS Trust (UK)

Sponsor details
Joint R&D Office, Mail Point 138
Southampton General Hospital
Tremona Road
Southampton
England
United Kingdom
SO16 6YD

Sponsor type

Hospital/treatment centre

Website
http://www.suht.nhs.uk/home.aspx

ROR
https://ror.org/0485axj58

Funder(s)

Funder type
Government

Funder Name
NIHR Health Technology Assessment Programme - HTA (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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	19/08/2013		Yes	No
Results article	results	23/04/2015		Yes	No
Results article	results	01/12/2015		Yes	No
Results article	results	01/02/2021	17/12/2020	Yes	No