# Randomised double-blind placebo-controlled trial of 40 mg/day of Atorvastatin on reduction in severity of SEPSIS in ward patients

Submission date	<b>Recruitment status</b> No longer recruiting	Prospectively registered	
06/07/2006		☐ Protocol	
Registration date	Overall study status Completed	Statistical analysis plan	
04/01/2007		[X] Results	
<b>Last Edited</b> 07/02/2013	Condition category Injury, Occupational Diseases, Poisoning	[] Individual participant data	

# Plain English summary of protocol

Not provided at time of registration

# Contact information

# Type(s)

Scientific

#### Contact name

Prof Fang Gao

#### Contact details

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# Additional identifiers

# EudraCT/CTIS number

2005-004636-52

IRAS number

ClinicalTrials.gov number

# Secondary identifying numbers

N/A

# Study information

### Scientific Title

## Acronym

**ASEPSIS** 

## Study objectives

Acute use of atorvastatin 40 mg/day in Accident and Emergency (A&E) and ward patients with sepsis will significantly reduce rates of sepsis converting to severe sepsis compared with placebo in previously non-statin treated patients.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Approved by South Birmingham Research Committee (CTA NUMBER 24698/0003/001-0001; MREC approval number 05/Q2707/369; EudraCT number 2005-004636-52).

## Study design

Double-blind randomised placebo-controlled trial interventional study using 40 mg oral atorvastatin once daily or 40 mg oral placebo once daily.

# 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

Sepsis

## Interventions

Patients will receive a single tablet of either atorvastatin 40 mg or identical placebo daily for the duration of their hospital stay or 28 days if earlier.

## Intervention Type

Drug

## **Phase**

**Not Specified** 

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

Atorvastatin

## Primary outcome measure

Sepsis converting to severe sepsis.

## Secondary outcome measures

- 1. Secondary outcomes are measured as admission to critical care.
- 2. Length of hospital stay.
- 3. 28 day mortality.
- 4. Eurogol questionnaire score

## Overall study start date

07/07/2006

## Completion date

01/01/2008

# **Eligibility**

## Key inclusion criteria

- 1. Aged more than 18 years
- 2. Patients history suggestive of a new infection such as pneumonia, empyema, Urinary Tract Infection (UTI), meningitis, skin/soft tissue inflammation, acute abdominal infection, bone/joint infection, wound infection, catheter or device infection or endocarditis
- 3. More than or equal to two of the following signs and symptoms of infection both present and new to the patient including:
- a. temperature more than 38°C or 36°C
- b. chills with rigors
- c. heart rate more than 90 beats per minute
- d. respiratory rate more than 20 bpm, or
- e. headache with stiff neck

## Participant type(s)

**Patient** 

#### Age group

Adult

## Lower age limit

18 Years

#### Sex

Both

## Target number of participants

414 participants, 207 in each study group across one site

## Key exclusion criteria

- 1. Signs of severe sepsis
- 2. Known active liver disease, alcohol abuse or persistantly abnormal liver function tests
- 3. Alanine aminotransferase more than two times the upper limit of normal laboratory ranges
- 4. Creatine kinase more than three times the upper limit of laboratory normal ranges
- 5. Pregnancy, breast feeding or women of child bearing potential not using adequate contraception
- 6. Previous adverse reaction to statins
- 7. Concomitant use of fibrates or other lipid lowering therapy
- 8. Administration of Atorvastatin was ceased less than or equal to two weeks prior to the trial
- 9. Concomitant use of erythromycin, telithromycin, clarithromycin, itraconazole, imidazoles, triazoles, cyclosporin or grapefruit juice
- 10. Patients in another clinical trial
- 11. Patients with terminal cancer
- 12. Known ileus
- 13. Failure to obtain written consent
- 14. Inability to swallow tablets safely

## Date of first enrolment

07/07/2006

## Date of final enrolment

01/01/2008

# Locations

## Countries of recruitment

England

United Kingdom

## Study participating centre Department of Anaesthesia

Birmingham United Kingdom B9 5SS

# Sponsor information

### Organisation

Heart of England Foundation Trust (UK)

## Sponsor details

Birmingham Heartlands Hospital Bordesley Green East Birmingham United Kingdom B9 5SS

## Sponsor type

Charity

## Website

http://www.heartofengland.nhs.uk/

# Funder(s)

## Funder type

Industry

## **Funder Name**

Pfizer Global Pharmaceuticals (International)

## Funder Name

The Moulton Charitable Fund (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?
Results article	results	11/12/2012		Yes	No