

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

Submission date
06/07/2006

Recruitment status
No longer recruiting

Prospectively registered

Protocol

Registration date
04/01/2007

Overall study status
Completed

Statistical analysis plan

Results

Last Edited
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

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Additional identifiers

Clinical Trials Information System (CTIS)
2005-004636-52

Protocol serial number
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

Study type(s)

Treatment

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(s)

Sepsis converting to severe sepsis.

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

1. Signs of severe sepsis
2. Known active liver disease, alcohol abuse or persistently 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

United Kingdom

England

Study participating centre

Department of Anaesthesia

Birmingham

United Kingdom

B9 5SS

Sponsor information

Organisation

Heart of England Foundation Trust (UK)

Funder(s)

Funder type

Industry

Funder Name

Pfizer Global Pharmaceuticals (International)

Funder Name

The Moulton Charitable Fund (UK)

Results and Publications

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