ISRCTN64637517 https://doi.org/10.1186/ISRCTN64637517

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

Submission date	Recruitment status
06/07/2006	No longer recruiting
Registration date	**Overall study status**
04/01/2007	Completed
Last Edited	**Condition category**
07/02/2013	Injury, Occupational Diseases, Poisoning

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
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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. Euroqol 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
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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