ISRCTN91327214 https://doi.org/10.1186/ISRCTN91327214

Simvastatin in community-acquired pneumonia

Submission date	Recruitment status	[X] Prospectively registered
05/02/2009	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
10/02/2009	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
13/01/2015	Infections and Infestations	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
FIS 070864

Study information

Scientific Title
Simvastatin in community-acquired pneumonia requiring hospitalisation: a randomised, double-blind, placebo-controlled trial

Study objectives
Simvastatin would be effective and safe to reduce time to clinical stability in patients with community-acquired pneumonia (CAP) requiring hospitalisation.

As of 03/02/2010 this record has been updated to reflect a change to the anticipated start and end dates of this trial; the initial trial dates were as follows:
Initial anticipated start date: 01/03/2009
Initial anticipated end date: 31/03/2011

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of the Hospital Universitari de Bellvitge (Comité Ètic d'Investigació Clínica) gave approval on 11th December 2008 (ref: AC099/08)

Study design
Randomised double-blind placebo-controlled 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
Community-acquired pneumonia

Interventions
Patients will be randomly assigned to receive simvastatin (20 mg/day) or placebo, that will be orally administered before the antibiotics in the Emergency Department and once daily thereafter for a total of 4 days.

Intervention Type

Drug

Phase
Phase II

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

Primary outcome measure
Time to clinical stability. Clinical stability will be measured daily during hospitalisation.

Secondary outcome measures
Determined at presentation in the Emergency Department before receiving simvastatin or placebo, and 48 hours after treatment administration:
1. Partial pressure of oxygen in the arterial blood (PaO2)/fraction of inspired oxygen (FiO2)
2. C-reactive protein
3. Tumour necrosis factor
4. Interleukin-6
5. Interleukin-10
6. Procalcitonin

Recorded from randomisation to 30 days (except in-hospital complications):
7. Need for intensive care unit (ICU) admission
8. Need for mechanical ventilation
9. In-hospital complications, measured throughout period of hospitalisation
10. Readmission (less than 30 days)
11. Early case-fatality rate (less than 48 hours)
12. Overall case-fatality rate (less than 30 days)

Overall study start date
01/12/2009

Completion date
31/12/2011

Eligibility

Key inclusion criteria
1. Immunocompetent adults (aged greater than 18 years, either sex)
2. Received a diagnosis of community-acquired pneumonia in the Emergency Department
3. Admitted to the hospital

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
376

Key exclusion criteria
1. Absence of written informed consent
2. Severe immunosuppression
3. Pregnancy
4. Not able to drink and eat
5. Prior statin therapy
6. Treatment with any of the following drugs: azoles, macrolides, amiodarone, antidepressant drugs and calcium channel blockers

Date of first enrolment
01/12/2009

Date of final enrolment
31/12/2011

Locations

Countries of recruitment
Spain

Study participating centre
Infectious Disease Department
Barcelona
Spain
08907

Sponsor information

Organisation
The Carlos III Health Institute (Instituto de Salud Carlos III) (Spain)

Sponsor details
Sinesio Delagado 4
Madrid
Spain
28029

Sponsor type
Research organisation

Website
http://www.isciii.es

ROR
https://ror.org/00ca2c886

Funder(s)

Funder type
Research organisation

Funder Name
The Carlos III Health Institute (Instituto de Salud Carlos III) (Spain)

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	06/01/2015		Yes	No