

Simvastatin in community-acquired pneumonia

Submission date 05/02/2009	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
Registration date 10/02/2009	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 13/01/2015	Condition category Infections and Infestations	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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

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 Delgado 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