Atorvastatin treatment and vaccination efficacy

Submission date	Recruitment status	Prospectively registered
23/01/2006	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
25/01/2006	Completed	Results
Last Edited	5 5	Individual participant data
21/09/2007		Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers N/A

Study information

Scientific Title

Study objectives

Statin treatment may modulate, either negatively or positively, antibody responses to vaccination antigens.

Ethics approval required

Old ethics approval format

Ethics approval(s)

The protocol was approved by the Ethics Committee of the Geneva University Hospital (CE-04-029) and written informed consent was obtained from all participants

Study design

Interventional, double-blind, randomised, placebo-controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Hepatitis A

Interventions

Subjects were immunised against hepatitis A and subsequently received atorvastatin (40 mg per day) or placebo for a period of 28 days after immunisation.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Atorvastatin

Primary outcome measure

The main outcome variable was the achievement of antibody levels greater than 20 IU/l against the hepatitis A virus one month after vaccination.

Secondary outcome measures

- 1. A secondary outcome variable was the mean log-transformed antibody titre
- 2. To document the effects of atorvastatin on total blood cholesterol, Low Density Lipoprotein Cholesterol (LDL-C), High Density Lipoprotein Cholesterol (HDL-C), triglycerides, and high-sensitivity C-Reactive Protein (hs-CRP)

Overall study start date

01/11/2004

Completion date

30/06/2005

Eligibility

Key inclusion criteria

Men and women who were greater than 18 years old were eligible for inclusion if they had neither morbidities nor immunity to hepatitis A

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

312

Key exclusion criteria

- 1. Anti-hepatitis A antibodies greater than 10 IU/l
- 2. Hypercholesterolemia
- 3. Hepatitis
- 4. Myositis
- 5. Chronic alcohol abuse
- 6. Pregnant or breast-feeding women
- 7. Volunteers on drug therapy except oral contraceptives

Date of first enrolment

01/11/2004

Date of final enrolment

30/06/2005

Locations

Countries of recruitment

Switzerland

Study participating centre Cardiology Division

Geneva Switzerland 1211

Sponsor information

Organisation

Geneva University Hospital (Switzerland)

Sponsor details

Cardiology Division
24 rue Micheli-du-Crest
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Sponsor type

Hospital/treatment centre

Website

http://www.cardiology-geneva

ROR

https://ror.org/01m1pv723

Funder(s)

Funder type

University/education

Funder Name

Geneva University Hospital (Switzerland) - Department of Medicine

Funder Name

University of Geneva Cardiology Foundation (GECOR) (Switzerland) - had no role in the study design, analysis of data or report writing

Results and Publications

Publication and dissemination planNot provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summaryNot provided at time of registration