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Atorvastatin treatment and vaccination efficacy

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