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Effects of a three-month course of rosuvastatin in patients with Systemic Lupus Erythematosus

Submission date	Recruitment status	[ ] Prospectively registered
12/03/2008	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
26/03/2008	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
26/03/2008	Musculoskeletal Diseases	[ ] Record updated in last year

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

Acronym
Rosuvastatin in SLE

Study objectives
Systemic lupus erythematosus (SLE) is a rheumatologic multi-systemic auto-immune disease particularly affecting joints, skin and kidneys. The aim of this trial was to investigate the effects of rosuvastatin on markers of lipid metabolism and inflammatory parameters in patients with SLE.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the Ethical Committee of the Slotervaart Hospital (The Netherlands) on the 29th November 2004.

Study design
Randomised, open-labelled, cross-over study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Systemic lupus erythematosus

Interventions
Rosuvastatin 10 mg once daily.

Intervention Type
Drug

Phase
Not Specified

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

Primary outcome measure
Measured at baseline and after three months of treatment:
1. Total cholesterol
2. Low density lipoprotein (LDL) cholesterol
3. C-reactive protein (CRP)
4. Tumour necrotising factor (TNF)

Secondary outcome measures
Measured at baseline and after three months of treatment:
1. Interleukin-6 (IL6), interleukin-10 (IL10), interleukin-8 (IL8)
2. Complement C3 and C4q
3. Anti-double stranded deoxyribonucleic acid (anti-dsDNA)
4. Urine protein

Overall study start date
01/01/2005

Completion date
01/01/2008

Eligibility

Key inclusion criteria
1. Patients with chronic, non-acute SLE
2. Greater than 18 years old, either sex

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
19

Key exclusion criteria
1. Use of statins
2. Pregnancy
3. Raised liver enzymes
4. Recent (less than three months) major surgery or myocardial infarction

Date of first enrolment
01/01/2005

Date of final enrolment
01/01/2008

Locations

Countries of recruitment
Netherlands

Study participating centre
Department of Internal Medicine
Maastricht
Netherlands
6229 HX

Sponsor information

Organisation
AstraZeneca (The Netherlands)

Sponsor details
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Zoetermeer
Netherlands
2700 AN
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Sponsor type
Industry

Website
http://www.astrazeneca.nl

ROR
https://ror.org/021tmn508

Funder(s)

Funder type
Industry

Funder Name

AstraZeneca (The Netherlands) - unrestricted research grant

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