

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

Submission date 12/03/2008	Recruitment status No longer recruiting	☐ Prospectively registered
		☐ Protocol
Registration date 26/03/2008	Overall study status Completed	☐ Statistical analysis plan
		☐ Results
Last Edited 26/03/2008	Condition category Musculoskeletal Diseases	☐ Individual participant data
		☐ 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

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.

Primary study design

Interventional

Study design

Randomised, open-labelled, cross-over study

Study type(s)

Treatment

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(s)

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)

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

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)

ROR

<https://ror.org/021tmn508>

Funder(s)

Funder type

Industry

Funder Name

AstraZeneca (The Netherlands) - unrestricted research grant

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration