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Atorvastatin treatment in Systemic Lupus Erythematosus patients

Submission date	Recruitment status	[ ] Prospectively registered
19/01/2011	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
18/02/2011	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
18/02/2011	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

Protocol serial number
N40201231/0460

Study information

Scientific Title
Influence of Atorvastatin on coronary calcifications and myocardial perfusion defects in Systemic Lupus Erythematosus patients: a prospective, randomised, double-masked, placebo-controlled study

Acronym
Atorvastatin-SLE

Study objectives
This study was conducted to determine the effect of atorvastatin treatment on multidetector computed tomography (MDCT)-based coronary calcium scoring and single photon emission computed tomography (SPECT)-assessed myocardial perfusion abnormalities in systemic lupus erythematosus (SLE) patients free of cardiovascular disease clinical symptoms.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethical Committee of the Jagiellonian University in Krakow, Poland, approved on the 12th January 2006 (ref: KBET/2/L/2006)

Primary study design
Interventional

Study design
Prospective randomised double-masked placebo-controlled study

Study type(s)
Treatment

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

Interventions
Atorvastatin treatment (40 mg/day) versus placebo. Total duration of treatment: 1 year. One year follow-up period.

Intervention Type
Drug

Phase
Phase IV

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

Primary outcome(s)
Measured at 0 and 12 months:
1. Calcium deposits in coronary arteries
2. Number of myocardial left ventricle segments with perfusion defects

Key secondary outcome(s)

Measured at 0, 3, 6, 12 months:
1. Symptoms of myocardial ischaemia
2. Need for reperfusion therapy
3. Deaths

Completion date
10/11/2010

Eligibility

Key inclusion criteria
1. Patients aged 20 - 73, either sex
2. Fulfilled at least 4 American College of Rheumatology (ACR) classification criteria for SLE
3. In stable clinical conditions (no need for immunosuppressive therapy intensification, i.e. current immunosuppressive drug dose increase or introduction of an additional immunosuppressive drug within last 3 months)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Known cancer
2. Clinical symptoms of coronary heart disease or heart failure (New York Heart Association [NYHA] III or IV class)
3. Renal failure (creatinine clearance less than 30 ml/min)
4. Respiratory failure

Date of first enrolment
01/01/2006

Date of final enrolment
10/11/2010

Locations

Countries of recruitment
Poland

Study participating centre
Pradnicka Str 80
Krakow
Poland
31-202

Sponsor information

Organisation
Polish Ministry of Science and Higher Education (Poland)

ROR
https://ror.org/05dwvd537

Funder(s)

Funder type
Government

Funder Name
Polish Ministry of Science and Higher Education (Poland) (ref: N40201231/0460)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration