

Statins for Digital Ulcers and Raynaud's Phenomenon in systemic sclerosis

Submission date
05/12/2007

Recruitment status
No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date
10/12/2007

Overall study status
Completed

☐ Statistical analysis plan

☒ Results

Last Edited
01/10/2008

Condition category
Musculoskeletal Diseases

☐ Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Anna Abou-Raya

Contact details
12 Heliopolis Street
Camp Cesar
Alexandria
Egypt
-

Additional identifiers

Study information

Scientific Title

Statins: a potentially useful therapeutic option in the management of systemic sclerosis-related Raynaud's phenomenon and digital ulcers

Acronym
SDURP

Study objectives

Systemic Sclerosis (SSc) is a chronic connective tissue disorder characterised by excessive cutaneous and visceral fibrosis, an aberrant immune activation and widespread, pronounced alterations in the microvasculature with structural and functional vasculopathy. Statins have an effect on endothelial dysfunction and thus may help ameliorate Raynaud's phenomenon and digital ulcers characteristic of SSc.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from the Ethics Committee of the Faculty of Medicine, University of Alexandria on the 13th of September, 2005.

Primary study design

Interventional

Study design

Randomised double-blind placebo-controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Systemic Sclerosis (SSc)

Interventions

The patients are divided into 2 groups:

Group 1: assigned to receive 40 mg/day of atorvastatin for four months

Group 2: assigned to identical placebo tablets for four months

Seventy-five healthy age-sex-matched volunteers serve the purpose of controls.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Atorvastatin

Primary outcome(s)

The primary outcome measure is the number of new digital ulcers occurring during the study period, measured monthly.

Key secondary outcome(s)

1. The Scleroderma Health Assessment Questionnaire subsets for dressing/grooming (SHAQ-DI)
2. Eating and hand grip
3. Assessment of safety and tolerability of the atorvastatin therapy

All secondary outcomes are measured monthly.

Completion date

05/05/2006

Eligibility

Key inclusion criteria

1. Raynaud's phenomenon
2. A history of a documented digital ulcer secondary to SSc within the last 12 months despite ongoing vasodilator therapy
3. Aged between 25 - 60 years, both male and female

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. Smoking
2. Diabetes mellitus
3. Hypercholesterolaemia
4. Hypertension
5. Cardiac insufficiency
6. Coexisting hepatic and renal diseases and drugs known to interact with statins

Date of first enrolment

30/09/2005

Date of final enrolment

05/05/2006

Locations

Countries of recruitment

Egypt

Study participating centre

12 Heliopolis Street
Alexandria
Egypt
-

Sponsor information

Organisation

University of Alexandria (Egypt)

ROR

<https://ror.org/00mzz1w90>

Funder(s)

Funder type

Other

Funder Name

Investigator initiated and funded (Egypt)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/09/2008		Yes	No