

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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

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.

Study design

Randomised double-blind placebo-controlled trial

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 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 measure

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

Secondary outcome measures

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.

Overall study start date

30/09/2005

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

Age group

Adult

Sex

Both

Target number of participants

80

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)

Sponsor details

Faculty of Medicine

12 Heliopolis Street

Camp Cesar

Alexandria

Egypt

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+20 (0)3 5924035

annaaraya@yahoo.com

Sponsor type

University/education

Website

<http://www.alexmed.org>

ROR

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

Funder(s)

Funder type

Other

Funder Name

Investigator initiated and funded (Egypt)

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

Study outputs

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