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

Submission date	Recruitment status	[ ] Prospectively registered
05/12/2007	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
10/12/2007	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
01/10/2008	Musculoskeletal Diseases	

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
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-
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Sponsor type
University/education

Website
http://www.alexmed.org

ROR
https://ror.org/00mzz1w90

Funder(s)

Funder type
Other

Funder Name
Investigator intiated 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