ISRCTN04371709 https://doi.org/10.1186/ISRCTN04371709

Focus On Capillaroscopic Ulcer index in Systemic sclerosis

Submission date	Recruitment status	[ ] Prospectively registered
10/02/2011	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
18/03/2011	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
14/08/2019	Musculoskeletal Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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8091

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Focus On Capillaroscopic Ulcer index in Systemic sclerosis: a national, multi-centre, prospective, observational, non-interventional pilot study

Acronym
FOCUS

Study objectives
To describe the change of the capillaroscopic skin ulcer risk index during the natural course of the disease and with bosentan treatment (in patients newly needing bosentan treatment by the decision of the physician).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Cantonal Ethics Committee Zürich, approved on 15.10.2010, KEK-ZH-Nr. 2010-0301/5

Study design
Multicentre prospective observational non-interventional pilot study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Screening

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Systemic sclerosis

Interventions
Capillaroscopic values (amount of capillaries, amount of megacapillaries and diameter of megacapillaries) are being documented over a one year period

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure

Change of the capillaroscopic skin ulcer risk index (CSURI) over time with or without specific treatment

Outcomes are measured at one year

Secondary outcome measures
1. Change of other capillaroscopic images, number of DU, appearance of new DU, change of Raynaud Condition Score, modified Rodnan skin score, amount of DU complications over time with or without specific treatment
2. Correlation of the CSURI with number of DUs, Raynaud condition score and other vascular complications
3. Comparison local versus central analysis of CSURI

Outcomes are measured at one year

Overall study start date
20/02/2011

Completion date
20/02/2013

Eligibility

Key inclusion criteria
1. Definitive diagnosis of systemic sclerosis (SSc) by the American College of Rheumatology (ACR) criteria
2. History of documented digital ischaemic ulcers secondary to SSc within the past year prior to enrolment or with at least one active digital ischaemic ulcer (DU) at enrolment
3. Signed patient informed consent form

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
60 - 100 participants

Total final enrolment
61

Key exclusion criteria
1. Patient refused to sign the patient informed consent
2. DUs due to a condition other than SSc
3. DU associated with calcinosis
4. Treatment with parenteral prostanoids or Tracleer®) within the past 3 months before

enrolment
5. Treatment with phosphodiesterase-5-inhibitors (PDE-5-I), except for intermittent treatment of male erectile dysfunction
6. Treatment with other Endothelin-receptor-antagonists (ERA)
7. Patients receiving any other experimental treatment
8. Patients receiving systemic antibiotics for infected ulcers
9. Patients with active renal crisis or advanced cardiopulmonary disease or who are otherwise clinically unstable

Date of first enrolment
20/02/2011

Date of final enrolment
20/02/2013

Locations

Countries of recruitment
Switzerland

Study participating centre
University Hospital Zürich
Zürich
Switzerland
8091

Sponsor information

Organisation
Actelion Pharma Schweiz AG (Switzerland)

Sponsor details
Stadtturmstrasse 5
Baden
Switzerland
5400

Sponsor type
Industry

Website
http://www.actelion.com/en/index.page

ROR
https://ror.org/001yedb91

Funder(s)

Funder type
Industry

Funder Name
Actelion Pharmaceuticals

Alternative Name(s)
Actelion Pharmaceuticals Ltd

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
Switzerland

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	25/10/2018	14/08/2019	Yes	No