Focus On Capillaroscopic Ulcer index in Systemic sclerosis

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

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr Oliver Distler

Contact details

University Hospital Zürich Gloriastrasse 25 Zürich Switzerland 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