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Study on the effect of Bosentan on trophic skin lesions in diabetic fOOT Syndrome (BOOTS)

Submission date
09/01/2012

Recruitment status
No longer recruiting

Registration date
20/02/2012

Overall study status
Completed

Last Edited
31/07/2014

Condition category
Nutritional, Metabolic, Endocrine

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Diabetes may trigger the development of a diabetic foot (open wounds on the foot). These wounds develop due to pathologically modified blood vessels with reduced blood circulation in the foot. They heal badly, are prone to infections and may require amputation of the foot. Therapies focus on surgical re-opening of the big blood vessels or on the application of vessel-dilating drugs. Bosentan is such a vessel-dilating drug. This study looks at how well bosentan works in improving the circulation of the foot and healing of the wounds.

Who can participate?
Male and female patients older than 18 years with a diabetic foot may participate.

What does the study involve?
All participants will receive bosentan for 4 months. Oxygen and blood supply of the skin, toe blood pressure, and size and pain of the wounds are measured 2 weeks, 1 and 4 months thereafter.

What are the possible benefits and risks of participating?
If bosentan works, circulation will improve and therefore the wounds may heal. The most frequent side effects of bosentan are headache, flush, leg swellings and anemia.

Where is the study run from?
University Hospital of Zürich (Switzerland).

When is the study starting and how long is it expected to run for?
The study started in January 2012 and planned to end patient enrolment in February 2013.

Who is funding the study?
This study is designed and organized by the University Hospital of Zürich, who are receiving the drug and financial support from Actelion, the licence owner of Tracleer®, which is the marketed product of bosentan. All study-related procedures and costs are covered by the University Hospital of Zürich.

Who is the main contact?
Dr Thomas Meier at the Clinic for Angiology

Contact information

Type(s)
Scientific

Contact name
Dr Thomas Meier

Contact details
Clinic for Angiology
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Zürich
Switzerland
CH-8091

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
BOOTS

Study information

Scientific Title
Open-label pilot study on the effect of Bosentan on trophic skin lesions in the diabetic fOOT Syndrome

Acronym
BOOTS

Study objectives
Bosentan improves peripheral tissue perfusion in diabetic patients with foot ulcers

Ethics approval required
Old ethics approval format

Ethics approval(s)
Cantonal Ethics Committee Zürich, 24/10/2011, ref: 2011-0216

Study design

Monocentric non-comparative open-label pilot study

Primary study design
Interventional

Secondary study design
Non randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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
Diabetic foot syndrome

Interventions
All enrolled patients will receive 62.5 mg bosentan (Tracleer®) twice a day (BID) for 4 weeks followed by 125 mg bosentan BID for 3 months. Total duration of treatment and follow up is 4 months.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Bosentan

Primary outcome measure
1. Transcutaneous oxygen tension
2. Reactive hyperemia

Measured at 2 weeks, 1 month and 4 months

Secondary outcome measures
1. Size and number of the ischemic skin lesions
2. Toe blood pressure
3. Local pain

Measured at 2 weeks, 1 month and 4 months

Overall study start date
20/01/2012

Completion date
30/05/2013

Eligibility

Key inclusion criteria
1. Provided written informed consent
2. Male and female patients aged > 18 years
3. With diabetic foot syndrome (irrespective of catheter technical or surgical revascularisation plans and irrespective of the presence of any infection)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
20

Key exclusion criteria
1. Trophic skin lesions due to other diseases than diabetes
2. Planned amputation within the following 4 months
3. Revascularisation within 4 weeks prior to inclusion
4. Systolic BP < 85 mm Hg
5. Hb <75% of the lower limit of normal
6. Severe malabsorption or any severe organ failure or any life-threatening state
7. Contraindications to the use of bosentan
8. Previous treatment with bosentan
9. Treatment with botulinus toxin, prostanoids, sildenafil or any other experimental treatment
10. Body weight< 40 kg
11. Patients unable to provide informed consent and comply with the protocol

Date of first enrolment
20/01/2012

Date of final enrolment
30/05/2013

Locations

Countries of recruitment
Switzerland

Study participating centre
Clinic for Angiology
Zürich
Switzerland
CH-8091

Sponsor information

Organisation
University Hospital Zürich (Switzerland)

Sponsor details
Rämistrasse 100
Zürich
Switzerland
CH-8091

Sponsor type
Hospital/treatment centre

Website
http://www.en.usz.ch/

ROR
https://ror.org/01462r250

Funder(s)

Funder type
Industry

Funder Name
Actelion Pharma Schweiz (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