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An urea, arginine and carnosine cream shows greater efficacy in the treatment of severe xerosis of the feet in type 2 diabetic patients in comparison with standard emollient glycerol cream.

Submission date
16/03/2015

Recruitment status
No longer recruiting

Registration date
24/04/2015

Overall study status
Completed

Last Edited
24/04/2015

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
Xerosis, is an abnormal dryness of the skin. It is one of the most common skin conditions in people with type 2 diabetes. Symptoms include dry, rough skin which, as the condition progresses, becomes red, scaly in appearance. Cracks and fissures may also develop and the skin becomes less elastic and less able to withstand trauma. This can all lead to breaking down of the skin and infections. As yet, there is no long term data available on the effects of emollients in treating severe kin xerosis of the foot in diabetics. Here, we want to investigate how well a urea, arginine and carnosine cream (UC) works in comparison with a glycerin-based emollient cream (SEC), in type 2 diabetics with severe xerosis of the feet.

Who can participate?
Adults aged 40-75 with type 2 diabetes and moderate-to-severe feet skin dryness

What does the study involve?
Participants are randomly allocated into one of two groups. Those in group 1 are treated with UC twice a day for 32 weeks. Those in group 2 are treated with SEC twice a day for 32 weeks. The severity of the xerosis is assessed using a 9-point Xerosis-Assessment-Scale (XAS) score and a 4-point Overall-Cutaneous-Score (OCS), at the start of the study, and then after 4, 12 and finally 32 weeks.

What are the possible benefits and risks of participating?
Benefits includes regular visits assess the skin condition of the feet and being supplied with emollients for the duration of the trial. No particular risks have been identified in taking part.

Where is the study run from?
Diabetic Foot Service, Monterotondo, Rome (Italy)

When is the study starting and how long is it expected to run for?
November 2013 to June 2014

Who is funding the study?
Isdin SA, Barcelona (Spain)

Who is the main contact?
Dr Massimo Milani

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
UR012014

Study information

Scientific Title
An urea, arginine and carnosine cream shows greater efficacy in the treatment of severe xerosis of the feet in type 2 diabetic patients in comparison with standard emollient glycerol cream: a randomized, 8-month, assessor-blinded, controlled trial.

Study objectives
We evaluated and compared the efficacy of 8-month treatment with urea 5%, arginine 0.4% and carnosine, 0.01% (UC) cream (Ureadin Podos Db cream, Isdin, Spain) in comparison with a

standard high content glycerol-based (40%) emollient topical product (SEC) (Neutrogena Norwegian Formula Dermatological Cream, Johnson and Johnson), in type 2 diabetic patients with skin xerosis of lower limbs.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Diabetic Foot Service Monterotondo Rome (Italy), October 2013

Study design
A mono-centre prospective, 8-month, randomised, parallel groups, assessor-blinded trial, carried out in a secondary-level diabetic clinic in Italy

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet

Health condition(s) or problem(s) studied
Type 2 diabetes mellitus and severe foot skin xerosis

Interventions
Urea 5%, arginine and carnosine cream vs glycerin 40% cream

Intervention Type
Drug

Phase
Phase III/IV

Drug/device/biological/vaccine name(s)
1. Ureadin Podos Db 2. Neutrogena

Primary outcome measure
Evolution of a 9-point grading Xerosis Assessment Scale (XAS) score (from 0 to 8) and of a 4-point grading Overall Cutaneous Score (OCS) (from 0 to 3) both evaluated at baseline, after 4, 12, and 32 weeks by an investigator unaware of treatment allocation.

Secondary outcome measures

1. The evolution of skin hydration and desquamation evaluated semi-quantitatively by means of Hydr8®, a bio-impedance analysis device, carried out at baseline and at week 32
2. The percentage of patients with very severe skin xerosis (i.e. XAS score>5) at baseline showing an improvement ≥3 points at the end of 32 weeks of treatment.

Overall study start date
01/11/2013

Completion date
30/06/2014

Eligibility

Key inclusion criteria
1. Adult men and women, aged between 40 and 75 years,
2. Confirmed diagnosis of type 2 diabetes
3. Moderate-to-severe feet skin dryness,
4. Not used any topical moisturizers on their feet for at least 2 weeks preceding enrolment visit

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
50

Key exclusion criteria
1. Insulin dependent diabetes mellitus
2. Presence or past history of foot ulcers lesions
3. Clinical evident peripheral arterial diseases (i.e. ankle/arm systolic blood pressure ratio <0.8)
4. Acute or chronic Charcot osteoarthropathy
5. Clinical significant neuropathy
6. Acute skin diseases and use of drugs that might affect sweating were the main exclusion criteria

Date of first enrolment
01/11/2013

Date of final enrolment
01/02/2014

Locations

Countries of recruitment

Italy

Study participating centre
Diabetic Foot Service
Monterotondo
Rome
Italy

Sponsor information

Organisation
Isdin SA

Sponsor details
Calle Provencals 33
Barcelona
Spain
20131

Sponsor type
Industry

ROR
https://ror.org/04dg86p75

Funder(s)

Funder type
Industry

Funder Name
Isdin SA, Barcelona (Spain)

Results and Publications

Publication and dissemination plan

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Stored in repository