

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	☐ Prospectively registered
		☐ Protocol
Registration date 24/04/2015	Overall study status Completed	☐ Statistical analysis plan
		☐ Results
Last Edited 24/04/2015	Condition category Nutritional, Metabolic, Endocrine	☐ 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 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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Protocol serial number
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

Study type(s)

Prevention

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(s)

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.

Key secondary outcome(s)

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.

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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

ROR

<https://ror.org/04dg86p75>

Funder(s)

Funder type

Industry

Funder Name

Isdin SA, Barcelona (Spain)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Stored in repository