Efficacy of topical urea in comparison with standard cream in foot skin xerosis in type 2 diabetic patients: A randomised investigator blinded study.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20899

Source
NTR

Brief title
Ureadin DB 01

Health condition

Skin hydratation in type 2 diabetic patient evaluated with standard DASI score (Dry Assessement Skin Xerosis)

Sponsors and support

Primary sponsor: Medical center.
Department of Podology Service
Monte rotondo Rome (Italy)
Source(s) of monetary or material Support: Investigator driven study (fund=initiator=sponsor)

Company Support regarding only study products (Urea lotion and control cream)

Intervention

Outcome measures

Primary outcome

1. DASI score;

2. Physician Global Assessement (score scale from 0 to 3).

Secondary outcome

Tolerability will be assesed with a patient Assessement score (from 0: very good tolerability tolerability to 3: not tolerated at all) at each visit.

Study description

Background summary

Xerosis is a common skin alteration found in diabetic patients.

Topical urea is considered a efficaious emollient treatment.

No comparative head-to-head trials have been performed to evaluate hydrating and emollient efficacy between topical products.

Study objective

Topical urea is a gold standard treatment for xerosis. Skin xerosis is commonly observed in diabetic subject. A correct hydratation of the skin is advised in order to reduce the risk of skin lesions such as ulcer. No comparative data are available comparing the hydrating and emollient efficacy of topical 10% urea in comparison with standard cream.

Study design

1. Baseline;

2. Week 2;

3. Week 4.

Intervention

Investigational product:

Topical urea in lotion (fluid cream) formulation 10% containing also arginine and carnosine.

Control:

Emollient cream containing glycerol.

Both products will be applied 2 times a day on the feet and in the 2/3 distal lower leg.

Contacts

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Eligibility criteria

Inclusion criteria

1. Type 2 diabetes in diet or oral treatment;

2. Hystory of diabetes since at least 6 years;

3. Age 40-80 years;

4. Men or women.

Exclusion criteria

1. Diabetic foot;

2. Severe neuropathy;

3. Severe vasculopathy;

4. Insulin treatment.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-01-2012
Enrollment:	40
Type:	Anticipated

Ethics review

Positive opinion

Date:	01-03-2012
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL3184
NTR-old	NTR3328
Other	: ADI-DB-01-12
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A