

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

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Topical urea is a gold standard treatment for xerosis. Skin xerosis is commonly observed in diabetic subject. A correct hydration of the skin is advised in order to reduce the risk of skin lesions such as ulcer. No comparative data are available...

|                             |                       |
|-----------------------------|-----------------------|
| <b>Ethische beoordeling</b> | Positief advies       |
| <b>Status</b>               | Werving gestart       |
| <b>Type aandoening</b>      | -                     |
| <b>Onderzoekstype</b>       | Interventie onderzoek |

## Samenvatting

### ID

NL-OMON20899

### Bron

Nationaal Trial Register

### Verkorte titel

Ureadin DB 01

### Aandoening

Skin hydration in type 2 diabetic patient evaluated with standard DASI score (Dry Assessment Skin Xerosis)

### Ondersteuning

**Primaire sponsor:** Medical center.

Department of Podology Service

Monte rotondo Rome (Italy)

**Overige ondersteuning:** Investigator driven study (fund=initiator=sponsor)

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

## Onderzoeksproduct en/of interventie

### Uitkomstmaten

#### Primaire uitkomstmaten

1. DASI score;<br>
2. Physician Global Assessment (score scale from 0 to 3).

## Toelichting onderzoek

### Achtergrond van het onderzoek

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.

### Doel van het onderzoek

Topical urea is a gold standard treatment for xerosis. Skin xerosis is commonly observed in diabetic subject. A correct hydration 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.

### Onderzoeksopzet

1. Baseline;
2. Week 2;
3. Week 4.

### Onderzoeksproduct en/of interventie

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.

## Contactpersonen

### Publiek

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### Wetenschappelijk

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## Deelname eisen

### Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Type 2 diabetes in diet or oral treatment;
2. History of diabetes since at least 6 years;
3. Age 40-80 years;
4. Men or women.

## Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Diabetic foot;
2. Severe neuropathy;
3. Severe vasculopathy;
4. Insulin treatment.

## Onderzoeksopzet

### Opzet

|                  |                        |
|------------------|------------------------|
| Type:            | Interventie onderzoek  |
| Onderzoeksmodel: | Parallel               |
| Toewijzing:      | Gerandomiseerd         |
| Blindering:      | Enkelblind             |
| Controle:        | Actieve controle groep |

### Deelname

|                         |                      |
|-------------------------|----------------------|
| Nederland               |                      |
| Status:                 | Werving gestart      |
| (Verwachte) startdatum: | 01-01-2012           |
| Aantal proefpersonen:   | 40                   |
| Type:                   | Verwachte startdatum |

## Ethische beoordeling

|                 |                  |
|-----------------|------------------|
| Positief advies |                  |
| Datum:          | 01-03-2012       |
| Soort:          | Eerste indiening |

## Registraties

### Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

### Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

### In overige registers

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

## Resultaten

### Samenvatting resultaten

N/A