

Doxycycline vs minocycline in the treatment of rosacea.

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We hypothesize that doxycycline and minocycline will be equally effective for the treatment of papulopustular rosacea.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON22785

Bron

Nationaal Trial Register

Verkorte titel

DoMino

Aandoening

Rosacea

Ondersteuning

Primaire sponsor: Academic Medical Center

Department of Dermatology

Overige ondersteuning: Academic Medical Center

Department of Dermatology

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

1. Lesion count;

2. The rosacea-specific Quality of life instrument (RosaQoL).

Toelichting onderzoek

Achtergrond van het onderzoek

Rosacea is a common and chronic dermatosis, mostly occurring in middle aged, fair-skinned men and woman, affecting up to 10% of the general population. Rosacea requires long-term treatment. According to the 2005 Cochrane review, accurate randomized controlled trials (RCT's) for the treatment of rosacea are lacking. More evidence is needed on systemic treatments that are widely used, including all tetracyclines. Recently, different doses of doxycycline have been studied. Its efficacy has been approved by several studies. And therefore the anti-inflammatory dose of doxycycline 40 mg has officially been accepted as treatment of papulopustular rosacea. Minocycline, has been used for decades by many patients but no studies to support its effectiveness are available.

Doel van het onderzoek

We hypothesize that doxycycline and minocycline will be equally effective for the treatment of papulopustular rosacea.

Onderzoeksopzet

Patients will be seen at screening and at 0, 4, 8 and 16 weeks. The follow up will be 12 weeks (last visit at week 28).

Onderzoeksproduct en/of interventie

1. Doxycycline 40 mg;
2. Minocycline 100 mg.

These will be given during a period of 16 weeks.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Subject is 18 years of age or older at baseline; both genders;
2. Subject has moderate to severe papulopustular rosacea, characterised by at least 8 lesions (papules and/or pustules), IGA higher than one and a CEA score higher than one, clinical confirmed by one of the investigators;
3. Subject has a negative urine pregnancy test at screening and uses a form of contraception;
4. Subject can fill out a Dutch questionnaire or has a person willing to translate the questions in their own language;
5. Subject has voluntarily signed and dated an informed consent prior to any study related procedure and is willing to comply with the requirements of this study protocol which has been approved by an Institutional Review Board (IRB)/Independent Ethics Committee (IEC).

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Subject is pregnant, nursing, or planning pregnancy while enrolled in the study and until 3 months after discontinuation of the study;
2. Presence of dermatoses that might interfere with the rosacea diagnosis or the evaluation of treatment results;
3. The initiation of a hormonal method of contraception within 3 months of baseline; or discontinuation during the course of study; or change in the actual product within 3 months of baseline or during the study;
4. Known hypersensitivity/allergy to tetracycline's;
5. Subject has used topical medications/treatments that could affect rosacea evaluation starting within 2 weeks of the first administration of study agent;
6. Subject has used systemic treatments (antibiotics, corticosteroids) for rosacea less than 4 weeks before baseline;
7. Subject has had facial laser-therapy less than 4 weeks before baseline or planned during study;
8. Subject has used any investigational drug within the previous 4 weeks or 5 times the half-life of the investigational agent prior to the first administration of study agent, whichever is longer;
9. Subject has used isotretinoin in the six months prior to randomization;
10. Subject is known to have hepatic impairment or to those receiving potentially hepatotoxic medicinal products;
11. Subjects is known to have, or is suspected to have, achlorhydria (production of gastric acid in the stomach is absent) or had surgery that bypasses or excludes the duodenum;
12. Current drug or alcohol abuse;
13. For any reason, subject is considered by the local investigator to be an unsuitable candidate to participate in this trial.

Onderzoeksopzet

Opzet

Type: Interventie onderzoek

Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	19-02-2011
Aantal proefpersonen:	80
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies	
Datum:	02-02-2011
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	NL2599
NTR-old	NTR2727
Ander register	MEC AMC : MEC 10/174
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten

N/A