Doxycycline vs minocycline in the treatment of rosacea.

No registrations found.

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

Summary

ID

NL-OMON22785

Source
NTR

Brief title
DoMino

Health condition

Rosacea

Sponsors and support

Primary sponsor: Academic Medical Center
Department of Dermatology
Source(s) of monetary or material Support: Academic Medical Center
Department of Dermatology

Intervention

Outcome measures

Primary outcome

1. Lesion count;

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

Secondary outcome

1. Patient’s Global Assessment (PaGA);

2. Investigators Global Assessment (IGA);

3. Clinician's Erythema Assessment (CEA);

4. Duration of remission;

5. Safety.

Study description

Background summary

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 papulopustualr rosacea. Minocycline, has been used for decades by many patients but no studies to support its effectiveness are available.

Study objective

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

Study design

Patients will be seen at screening and at 0, 4,m8 and 16 weeks. The follow up wil be 12 weeks (last visit at week 28).

Intervention

1. Doxycycline 40 mg;

2. Minocycline 100 mg.

These will be given during a period of 16 weeks.

Contacts

Public
P.O Box 22660
M.M.D. Linden, van der
Department of Dermatology
Academic Medical Center
Meibergdreef 9
Amsterdam 1100 DD
The Netherlands
+31 (0)20 5662530
Scientific
P.O Box 22660
M.M.D. Linden, van der
Department of Dermatology
Academic Medical Center
Meibergdreef 9
Amsterdam 1100 DD
The Netherlands
+31 (0)20 5662530

Eligibility criteria

Inclusion criteria

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 anticonception;

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).

Exclusion criteria

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.

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):	19-02-2011
Enrollment:	80
Type:	Anticipated

Ethics review

Positive opinion

Date:	02-02-2011
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	NL2599
NTR-old	NTR2727
Other	MEC AMC : MEC 10/174
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A