Doxycycline versus minocycline in the treatment of rosacea: a randomized controlled trial.

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To compare the efficacy of doxycycline 40 mg (Efracea) versus minocycline 100 mg treatment in adult patients with papulopustular rosacea.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Epidermal and dermal conditions
Study type	Interventional

Summary

ID

NL-OMON34060

Source
ToetsingOnline

Brief title
DoMino

Condition

- Epidermal and dermal conditions

Synonym
acne rosacea, papulopustuleuze rosacea

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: chan fleury

Intervention

Keyword: doxycycline, minocycline, rosacea

Outcome measures

Primary outcome

*Lesion count

*The rosacea-specific Quality of life instrument (RosaQol)

Secondary outcome

*Skindex-29 (=quality of life, not specific for rosacea)

*Patient*s Global Assessment (PaGA)

*Investigators Global Assessment (IGA)

*Clinician's Erythema Assessment (CEA)

*Duration of remission

*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. It*s characterized by four primary features affecting primarily de convexities of the central face in a symmetrical distribution: flushing, erythema, papules/ pustules and telangiectasia. Rosacea is a chronic disease and therefore requires long-term treatment. As rosacea has a great impact on quality of life, rosacea management should involve strategies for improving the quality of life. Based on the severity grade and the rosacea subtype, there are different therapy options like topical, systemic, surgical and laser therapy. According to the 2005 Cochrane review, accurate randomized controlled trials (RCT*s) for most treatments 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.

Study objective

To compare the efficacy of doxycycline 40 mg (Efracea) versus minocycline 100 mg treatment in adult patients with papulopustular rosacea.

Study design

A randomized controlled, mono-centre, two-arm, single-blinded, open-label trail, during 28 weeks, consisting of 16 weeks of treatment and a 12-week follow-up period without treatment, to evaluate the efficacy and safety of doxycycline (1dd 40 mg) versus minocycline (1dd 100 mg) treatment in two randomized groups (ratio 1:1) of adult patients with chronic, moderate to severe rosacea.

Intervention

During 16 weeks patients will receive daily oral doxycycline 40 mg treatment (Arm 1) or daily oral minocycline 100 mg (Arm 2).

Study burden and risks

Patients will visit the clinic approximately 6 times. At screening, at baseline and at 4,8,16,28 weeks. During these visits, the rosacea will be scored, using different scoring scales. Secondly, patients will fill out several questionnaires about their quality of life. Patients will also receive a diary for detailing the intake of their assigned medication, concomitant medications and possible adverse events. Additional visits may be required between the scheduled visits to assess any adverse events requiring close monitoring. Patients will be treated with either doxycycline or minocycline. Both medicines are broadly used in the treatment of rosacea. Therefore, possible adverse events are well-known and easily recognized. With the low doses used in this study, we expect the adverse events will be limited.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

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 two 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 phase:	3
Study type:	Interventional
Intervention model:	Parallel
Masking:	Single blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	21-04-2011
Enrollment:	80
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Efracea
Generic name:	doxycycline
Registration:	Yes - NL outside intended use
Product type:	Medicine
Brand name:	minocycline
Generic name:	minocycline
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	22-07-2010
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	18-04-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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
EudraCT	EUCTR2010-021150-19-NL
CCMO	NL32812.018.10