De behandeling van Rosacea met Oxofulleram. Een pilotonderzoek naar de klinische toepasbaarheid van Oxofulleram.

Published: 02-12-2014
Last updated: 21-04-2024

The hypothesis of this study is that the regular topical application of Oxofulleram in patients with rosacea results in a reduction of the clinical symptoms.

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

Summary

ID

NL-OMON53162

Source
ToetsingOnline

Brief title
Solenne-OxoF-Rosa

Condition

- Epidermal and dermal conditions

Synonym
Papulopustular Rosacea, Rosacea

Research involving
Human

Sponsors and support

Primary sponsor: Solenne BV
Source(s) of monetary or material Support: de opdrachtgever en een provinciale

subsidie

Intervention

Keyword: Oxofulleram, Pilot Study, Rosacea

Outcome measures

Primary outcome

Primary endpoint:

- the difference in the clinical scores of rosacea of the treated and the

placebo-treated

sides of the face on weeks 2, 4, 6, 8, 10 and 12.

- The difference in the rosacea patients self-evaluation scores of the treated

and the placebo-treated sides of the face on weeks 1, 2, 3, 4, 5, 6, 7, 8, 9,

10, 11 and 12.

Secondary outcome

Side effects

Study description

Background summary

Rosacea is a common dermatological condition which is characterized by facial papulopustels and erythema. Solenne BV has developed a patented fullerene called Oxofulleram. The cosmetic use of Oxofulleram by patients with rosacea yielded remarkable positive results. In order to investigate the clinical potential of Oxofulleram Solenne wants to apply the compound in a clinical proof of concept pilot study.

Study objective

The hypothesis of this study is that the regular topical application of Oxofulleram in patients with rosacea results in a reduction of the clinical

symptoms.

Study design

Patients will be recruited from the outpatient clinic of the Department of Dermatology at the University Medical Center Groningen. At home the patients will apply Oxofulleram (Combray ®) unilateral twice a day while at the other side of the face a placebo (grapeseed oil) is applied. Thus, in this study with a blinded observer, each patient, serves as his or her own control. The duration of the intervention period is six weeks with a follow up period of six weeks. The patients are seen by by the researchers every two weeks and bilaterally scored on the severity and the development of the disease. Furthermore, the patients weekly fill in a self-evaluation form.

Intervention

The intervention consists of twice daily (morning and evening) unilaterally applying Oxofulleram (dissolved in grape seed oil) on the face. On the other side of the face is applied a placebo which consists of grape seed oil.

Study burden and risks

After the intervention period of 6 weeks, there is a follow-up period of 6 weeks to assess the remission of the disease. During the total study duration of 12 weeks, the patient should refrain from his or her usual medication. Therefore, it may happen that the patients* face may show a temporary worsening of the clinical picture.

Contacts

Public
Solenne BV

Zernikepark 6
Groningen 9747 AN
NL
Scientific
Solenne BV

Zernikepark 6
Groningen 9747 AN
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- a diagnosis of papulopustular rosacea;
- the conventional treatments of rosacea should be stopped with a wash-out period of one month;
- age 18-65 years;
- male and female;
- women of childbearing age use double barrier contraception

Exclusion criteria

- Patients with non papulopustular subtypes of rosacea are excluded from the study;
- Patients with other facial dermatoses (acne, perioral dermatitis, eczema);
- Age: younger than 18 and older than 65 years;
- Pregnancy;
- Patients treated with an EGFR inhibitor for an oncological condition are excluded from the study;
- Legally incapable.

Study design

Design

Study phase:	2
Study type:	Interventional

Intervention model:	Other
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	27-01-2015
Enrollment:	20
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Oxofulleram
Generic name:	tbd

Ethics review

Approved WMO Date:	02-12-2014
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	27-01-2015
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	15-06-2015
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	EUCTR2014-004962-76-NL
CCMO	NL49195.042.14