A phase 2, randomized, vehicle and ketoconazole-controlled, evaluator-blinded, study to explore the efficacy, pharmacodynamics and safety of omiganan 1.75% topical gel BID in patients with mild to moderate facial seborrheic dermatitis.

Published: 02-08-2018
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Primary Objective* To explore the efficacy and pharmacodynamic effects of omiganan topical gel in facial seborrheic dermatitis Secondary Objectives* To explore skin and faecal microbiome in patients with seborrheic dermatitis * To evaluate the...

Ethical review	Approved WMO
Status	Completed
Health condition type	Skin and subcutaneous tissue disorders NEC
Study type	Interventional

Summary

ID

NL-OMON48780

Source
ToetsingOnline

Brief title
Omiganan BID in patients with facial seborrheic dermatitis

Condition

- Skin and subcutaneous tissue disorders NEC

Synonym
seborrheic dermatitis; seborrhoea

Research involving
Human

Sponsors and support

Primary sponsor: Maruho Co., Ltd.
Source(s) of monetary or material Support: Maruho Co.;Ltd.

Intervention

Keyword: Omiganan, Seborrheic dermatitis

Outcome measures

Primary outcome

Pharmacodynamic endpoints

* Microbiome (for skin: microbiota and mycobiota, for gut: microbiota)

* Mycology (mycobiome and culture)

* Sebum measurement (Sebumeter)

* Skin barrier function by Trans Epidermal Water Loss (TEWL)

* Skin morphology by Optical coherence tomography (OCT)

* Changes in stratum corneum lipid composition by liquid chromatography-mass

spectrometry (LC-MS)

Efficacy endpoints

* Seborrheic dermatitis area severity index (SDASI)

* Investigator Global Assessment (IGA)

* Area of involvement (% body surface area affected by facial SD)

* Patient reported outcomes (5D- itch scale, daily NRS itch, DLQI)

* Standardized facial photography by VISIA-CR

Tolerability / safety endpoints

Adverse events (AE) will be collected throughout the study, at every study

visit. Laboratory safety testing, 12-Lead ECGs and vital signs will be

performed at screening and at end of study (EOS).

Secondary outcome

N.A.

Study description

Background summary

Seborrheic dermatitis (SD) is a common dermatological condition which involves erythema, scaling/flaking and pruritus. It affects mainly seborrheic anatomical sites of the face, retro-auricle area and the upper chest. When present on the scalp SD is distinctly considered separately as a non-inflammatory variant of SD, pityriasis capitis (PC). In infants, the incidence can be up to 42%. In adolescents and adults the incidence is 1% to 3% of the general population. Treatment modalities are mainly topical and include anti-fungals, topical steroids and immunomodulatory therapies. Despite this, the burden of disease is considered to be high (Borda LJ and Wikramanayake TC, 2015. Berk T and Scheinfeld N 2010).

The pathogenesis of SD is not completely understood. Studies have identified several factors, including fungal colonization (in particular with yeasts of the genus Malassezia), sebaceous gland activity and host factors (Borda LJ and Wikramanayake TC, 2015). Recently interactions between the host and microorganisms have been reported, with bacteria having a strong association with severity of PC. The relationship between Staphylococcus and Propionibacterium were mutual inhibitory. The microbiome in PC is characterized by a preponderance of Staphylococcus and lesser diversity compared to normal scalp (Xu Z, 2016).

Study objective

Primary Objective
* To explore the efficacy and pharmacodynamic effects of omiganan topical gel in facial seborrheic dermatitis
Secondary Objectives
* To explore skin and faecal microbiome in patients with seborrheic dermatitis
* To evaluate the safety and tolerability of omiganan topical gel in facial seborrheic dermatitis

Study design

A phase 2, randomized, vehicle and ketoconazole-controlled, evaluator-blinded study to explore the efficacy, pharmacodynamics and safety of omiganan 1.75% topical gel BID in patients with mild to moderate facial seborrheic dermatitis.

Intervention

CLS001 is a topical gel containing omiganan, a 12-amino-acid cationic peptide. A previous phase 2 drug study in atopic dermatitis patients studied dosage of 1 and 2.5 % QD with a maximum treated body surface of 1%, whereas this phase II study will dose 1.75% BID. The maximum treated body surface area will be approximately 5% (face).

The maximum dose of topical omiganan is estimated at: 905 cm2 (5% total average BSA of an adult with a total body surface area of 1.81 m2) x 0.44 mg/cm2 (average amount applied per cm2) x 0.0175 (dose of 1.75% w/w) x 2 (BID) = 14 mg per day.

Study burden and risks

The risks associated with the topical administration of CLS001 to humans has been identified in over 4,000 subjects in total in twenty six clinical trials completed with topical applications of omiganan in formulations ranging from 0.5% to 3% in an aqueous gel and from 1% to 5% in an alcoholic solution for the indications of various indications including treatment of the inflammatory lesions of rosacea, treatment of acne, treatment of atopic dermatitis and treatment of S. aureus in the nasal carriage. Omiganan when applied topically to intact or abraded skin, intranasally or at peripheral and central venous catheter sites appears to be safe and well tolerated. In addition, omiganan was only rarely detected in the plasma of subjects after topical application to intact or abraded skin, to the nasal mucosa or at peripheral catheter sites. The risk of topical application to a very restricted lesional area can be considered minimal. Potential beneficial effects on seborrheic dermatitis are to be explored in this study. Therefore, providing the protocol is adhered to, careful observation and medical management will minimize any associated risk in this study.

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

For enrollment of subjects the following criteria must be met:
1. Male and female subjects with mild to moderate facial SD (IGA 2 or 3), *18 years of age, inclusive. The health status is verified by absence of evidence of any clinical significant active or uncontrolled chronic disease other than SD following a detailed medical history, a complete physical examination including vital signs, 12-lead ECG, hematology, blood chemistry, virology and urinalysis;
2. Confirmed SD diagnosis by dermatologist
3. Significant facial SD affected area as judged by the investigator or medically qualified designee.
4. Able to participate and willing to give written informed consent and to comply with the study restrictions;
5. Willing to refrain from using other SD treatments in the local treatment area
6. Subjects and their partners of childbearing potential must use effective contraception, for the duration of the study and for 3 months after the last dose.

Exclusion criteria

Eligible subjects must meet none of the following exclusion criteria:
1. Any current and / or recurrent clinical significant skin condition other than SD;
2. Ongoing use of prohibited SD medication. Washout periods prior to baseline are as follows;
a. Topical steroids, antibiotics, antifungals or other (OTC) topical therapies: 2 weeks
b. Systemic steroids, antibiotics, antifungals or other systemic therapies: 4 weeks;
c. Phototherapy: 3 weeks;
d. Regular use of shampoo for the treatment of PC (including but not limited to OTC zinc pyrithione shampoo), soap for the treatment of seborrheic dermatitis: 2 weeks
e. Changing a soap, method for daily facial and hair washing: 1 week
3. Known hypersensitivity to the compounds or excipients of the compounds;
4. Tanning due to sunbathing, excessive sun exposure or a tanning booth within 3 weeks of enrollment;
5. Pregnant, a positive pregnancy test, intending to become pregnant, or breastfeeding;
6. Participation in an investigational drug or device study within 3 months prior to screening or more than 4 times in the past year;
7. Loss or donation of blood over 500 mL within three months (males) or four months (females) prior to screening.

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	05-09-2018
Enrollment:	36
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Omiganan topical gel
Generic name:	Omiganan

Ethics review

Approved WMO Date:	02-08-2018
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	05-09-2018
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	26-10-2018
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	12-08-2019
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	27-08-2019

Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

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	EUCTR2017-003106-41-NL
CCMO	NL62759.056.18

Study results

Date completed:	06-01-2020
Results posted:	05-10-2020

First publication
01-01-1900