A Phase 3, Randomized, Vehicle-Controlled, Double-Blind, Multicenter Study to Evaluate the Safety and Efficacy of Once-Daily CLS001 Topical Gel Versus Vehicle Administered for 12 Weeks to Subjects with Papulopustular Rosacea with a 4 Week Follow-up Period

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To evaluate the safety and efficacy of once daily application of omiganan topical gel compared to vehicle topical gel in subjects with papulopustular rosacea

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

Summary

ID

NL-OMON42482

Source
ToetsingOnline

Brief title
CLS-CO-PR-005

Condition

- Epidermal and dermal conditions

Synonym
acne rosacea

Research involving
Human

Sponsors and support

Primary sponsor: Cutanea Life Sciences
Source(s) of monetary or material Support: Cutanea Life Sciences

Intervention

Keyword: Papulopustular Rosacea

Outcome measures

Primary outcome

1. Absolute change in inflammatory lesion count at week 12; 2. IGA: 2 grade

reduction at Week 12; Clear or Almost Clear (IGA of 0 or 1) rating at Week 12.

Secondary outcome

Not applicable

Study description

Background summary

There is no cure for rosacea and treatment is aimed at alleviating the symptoms. Topical or oral medications are generally prescribed for mild to moderate papulopustular rosacea. The topical medications include: metronidazole, azelaic acid, ivermectin, sodium sulfacetamide and sulfur, erythromycin, and tretinoin. Oral medications prescribed for severe disease include doxycycline at microbial and subantimicrobial doses and, minocycline. Isotretinoin, although not FDA approved for the treatment of rosacea, has also been prescribed when other agents have failed. In particular, treatments for severe rosacea are inadequate, and isotretinoin use has been recommended with increasing frequency in this patient population. Hence, topical Omiganan has the potential to become an important addition to the dermatologist*s armamentarium in treating severe rosacea.

The exact cause of rosacea is unknown and may be in due in part to an inflammatory process. Recent research has shown that cationic peptides such as omiganan may have anti-inflammatory properties and may play a role in

inhibiting the inflammatory response. Omiganan may also prevent the inflammatory cascade that is theorized to lead to the signs and symptoms of rosacea. A possible anti-inflammatory activity of omiganan is suggested by the observation of a reduction in inflammatory acne lesion counts with omiganan in two Phase 2 clinical trials. However, the exact mechanism of action is undetermined.

Omiganan pentahydrochloride topical gel has been evaluated in human clinical studies at concentrations of 0.5%, 1.0%, 2.5% and 3% in Phase 1 studies; at concentrations of 1.0%, 1.75% and 2.5% in Phase 2 studies; and at concentrations of 1.0% in a Phase 3 study. In these studies, including two Phase 2 studies of omiganan topical gel applied to the face of subjects with moderate to severe papulopustular rosacea, omiganan was found to be safe, and well tolerated. In the most recent Phase 2 study in which vehicle or omiganan pentahydrochloride topical gel 1.0%, 1.75% or 2.5% was applied once daily to the face of 240 moderate to severe rosacea subjects for 12 weeks, the most frequently reported adverse events were headache, sinusitis, and upper respiratory tract infections. Most treatment emergent adverse events were considered mild or moderate in severity.

Study objective

To evaluate the safety and efficacy of once daily application of omiganan topical gel compared to vehicle topical gel in subjects with papulopustular rosacea

Study design

Double-blind, multicenter, randomized, vehicle-controlled, parallel comparison.

Intervention

During the study, blood samples will be taken: 6 times over the course of the study (minimum 6 ml and maximum 17 ml each time).

Study burden and risks

Information available in Information Sheet for participants

Contacts

Public
Cutanea Life Sciences

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Scientific
Cutanea Life Sciences

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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. Subjects who provided written informed consent to participate in the study.;2. Healthy, male and non-pregnant female subjects, 18 years of age or older.;3. A diagnosis of papulopustular rosacea with *30 inflammatory facial lesions (papules, pustules) at Baseline. Subjects must have no more than 2 nodular lesions, at Baseline.;4. Subjects with the presence of telangiectasia at Baseline.;5. Subjects with an erythema score of at least 2 on the Investigator Assessment of Erythema (IAE) scale at Baseline.;6. Subjects with a grade 4 (severe rosacea) on the 5-point Investigators Global Assessment (IGA) scale at Baseline.;7. Non-nursing, female subjects of child bearing potential, who are using a highly effective form of birth control or females not of childbearing potential due to menopause (must be postmenopausal for at least one year).;* Highly effective methods of birth control are defined as those, alone or in combination, that result in a low failure rate (i.e. less than 1% per year) when used consistently and correctly. Forms of birth control include: Oral (birth control pills), Intravaginal: (e.g. NuvaRing®), Implantable (e.g. Norplant®), injectable (e.g. Depo-Provera®) or transdermal (e.g. Ortho Evra®) contraception; intrauterine device (IUD); double-barrier (diaphragm or condom with spermicidal gel or foam); for two months prior to study enrollment (see exclusion criteria #6) or a vasectomized partner or true abstinence (in line with preferred and usual lifestyle of subject) with an acceptable form of birth control should the subject become sexually active. Periodic abstinence (e.g., calendar, ovulation,

symptothermal, post-ovulation methods) and withdrawal are not acceptable methods of contraception. All female subjects of child bearing potential must undergo an in-office, highly sensitive urine pregnancy test, with a negative result, prior to being randomized to receive study drug. In addition, women of childbearing potential must agree to have a highly sensitive urine pregnancy test at the end of the study.;8. Subjects who have used the same brand of soap, make-up, hair products, or shaving lotion/foam/cream/gel for a period of at least four weeks prior to the Baseline Visit and agree not to change these product brand/types during the study.;9. Male subjects who are willing to shave, if applicable, at approximately the same time every day.;10. Subjects who are willing and able to return to the study clinic for the designated study visits.;11. Subjects who are willing to refrain from sunbathing, using sun tanning booths/beds, or excessive exposure to the sun for the duration of the study.;12. Subjects who are willing to comply with the protocol and visit requirements.

Exclusion criteria

1. Subjects with clinically significant abnormal findings at the Baseline/Day 1 Visit that would require a new intervention or treatment or a change in treatment that would in the opinion of the investigator supersede participation in the clinical trial.;2. Subjects with steroid rosacea or subtype 3 (phymatous rosacea).;3. Subjects with nodular rosacea (defined as more than 2 lesions greater than 5 mm).;4. Subjects with underlying diseases or other dermatological conditions, such as; atopic dermatitis, perioral dermatitis, or seborrheic dermatitis, which requires the use of interfering topical or systemic therapy or may interfere with the rosacea diagnosis or its assessment.;5. Subjects using concomitant treatments that may influence study end points within 2 weeks of the Baseline Visit (e.g., facial or chemical peels, dermal fillers, acne surgery, intralesional steroids, spironolactone, debridement, cryotherapy, dermabrasion, X-ray, laser therapy or UV therapy).;6. If using estrogens or progesteronal agents (e.g, Gynogen, Valergen, Depo-Testadiol, Depogen, birth control pills), for less than 2 months prior to the Baseline Visit. (Subjects using estrogens for 2 months or more need not be excluded unless the subject expects to change dose, drug, or discontinue estrogen use during the study. See Inclusion #7);7. Subjects with known allergies to the active ingredient or any of the excipients. (See Section7.6.2);8. Subjects who have not undergone the specified washout period(s) for the following topical preparations applied to the face or subjects who require the concomitant use of any of the following topical preparations/treatments applied to the face:;Product Washout Period;(Prior to Baseline/First Dose);* Abradants, astringents, toners, facials, masks, or moisturizers;containing retinols, AHA (alpha hydroxyl acids),;salicylic acids, 1 week;* Tanning booths/beds 2 weeks;* Antibiotics (other than topical ocular application) 2 weeks;* Antimicrobial soaps 2 weeks;* Corticosteroids 2 weeks;* Other anti-inflammatories 2 weeks;* Other rosacea treatments (e.g., azelaic acid,;metronidazole, ivermectin, sulfacetamide) 2 weeks;* Retinoids 4 weeks;9. Subjects who have not undergone the specified washout period(s) for the following systemic treatments or subjects who require the concomitant use of any of the following systemic treatments:;Product Washout Period;(Prior to Baseline/First Dose);* Antibiotics 4 weeks;* Corticosteroids 4 weeks;* Retinoids 12 weeks;10. Female subjects who are pregnant, nursing, or planning a pregnancy within the study period.;11. Subjects who have a beard, or excessive facial hair. A moustache will be allowed, if in the investigator*s judgment it does not impair the assessment of

rosacea.;12. Subjects using an investigational drug within 30 days of the Baseline Visit or who are currently participating in an investigational study. Use of an investigational drug/device and/or participation in another investigational study is prohibited during this study.;13. Subjects who currently abuse alcohol or drugs or who have a history of chronic alcohol or drug abuse with in the past year.;14. Subjects who have a chronic medical condition that may require the use of a prohibited medication to treat new symptoms or exacerbations.

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-12-2015
Enrollment:	40
Type:	Anticipated

Medical products/devices used

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

Ethics review

Approved WMO

Date:	26-10-2015

Application type:	First submission
Review commission:	IRB Nijmegen: Independent Review Board Nijmegen (Wijchen)
Approved WMO Date:	23-12-2015
Application type:	First submission
Review commission:	IRB Nijmegen: Independent Review Board Nijmegen (Wijchen)
Approved WMO Date:	17-05-2016
Application type:	Amendment
Review commission:	IRB Nijmegen: Independent Review Board Nijmegen (Wijchen)
Approved WMO Date:	03-10-2016
Application type:	Amendment
Review commission:	IRB Nijmegen: Independent Review Board Nijmegen (Wijchen)
Approved WMO Date:	20-10-2016
Application type:	Amendment
Review commission:	IRB Nijmegen: Independent Review Board Nijmegen (Wijchen)
Approved WMO Date:	01-05-2017
Application type:	Amendment
Review commission:	IRB Nijmegen: Independent Review Board Nijmegen (Wijchen)
Approved WMO Date:	06-06-2017
Application type:	Amendment
Review commission:	IRB Nijmegen: Independent Review Board Nijmegen (Wijchen)

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	EUCTR2015-002920-23-NL
CCMO	NL55272.072.15