A PHASE 2, RANDOMIZED, VEHICLE-CONTROLLED, DOUBLE-BLIND, PARALLEL-GROUP STUDY TO EXPLORE THE PHARMACODYNAMICS, SAFETY AND EFFICACY OF TOPICAL OMIGANAN IN PATIENTS WITH EXTERNAL GENITAL WARTS.

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Primary Objectives* To explore the pharmacodynamic effects of topically applied omiganan in patients with external genital warts* To explore clinical efficacy of omiganan compared to placebo in patients with external genital warts.Secondary...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON43535

Source
ToetsingOnline

Brief title
Omiganan in patients with external genital warts.

Condition

- Other condition
- Female reproductive tract infections and inflammations

Synonym

Condylomata acuminata, External genital warts

Health condition

voortplantingsstelsel- en borstaandoeningen; voortplantingsstelselinfecties en -ontstekingen, mannelijk

Research involving
Human

Sponsors and support

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

Intervention

Keyword: External Genital Warts, Omiganan

Outcome measures

Primary outcome

Exploratory clinical efficacy endpoints / Pharmacodynamic endpoints

* Count of all lesions visible

* Percent clearance of treated lesions

o Proportion of all baseline lesions cleared

o Proportion of all (baseline and new) lesions cleared

o Proportion of subjects with cleared treated lesions (90% / 75% / 50%)

* Absolute reduction in target wart size

o Diameter (mm)

o Height (mm)

o Volume (mm3)

* Target wart size reduction (percentage)

* Change in patient-reported outcomes (QoL and patient-reported clearance)

* Histology / Local immunity status

* Wart size of all warts of interest (target and biopsy warts) by standardized

clinical 2D and 3D photography

* HPV viral load assessment of primary wart by quantitative PCR including HPV

genotyping

in swabs

* Change from baseline in the HPV viral load (nominal, natural log transformed,

and natural

log of viral load per DNA copies) as determined by qPCR

* Mean HPV viral load (nominal, natural log transformed, and natural log of

viral load per DNA

copies) at treatment weeks and overall study

* Biomarkers in biopsies (IFN-*, IFN-beta, IL-1beta, IL-8)

Tolerability / safety endpoints

* Compliance with dosing instructions (patient completed e-diary)

* Adverse events (AE)

* Laboratory safety testing

o Chemistry

o Hematology

o Urinalysis

* Treatment-emergent (serious) adverse events ((S)AEs).

* Vital signs

o Pulse Rate (bpm)

o Systolic blood pressure (mmHg)

o Diastolic blood pressure (mmHg)

o Temperature

* Electrocardiogram (ECG)

o Heart Rate (HR) (bpm), PR, QRS, QT, QTcB, QTcF

Secondary outcome

Compliance with dosing instructions (patient completed e-diary)

Adverse events (AE)

Laboratory safety testing

o Chemistry

o Hematology

o Urinalysis

Treatment-emergent (serious) adverse events ((S)AEs).

Vital signs

o Pulse Rate (bpm)

o Systolic blood pressure (mmHg)

o Diastolic blood pressure (mmHg)

o Temperature

Electrocardiogram (ECG)

o Heart Rate (HR) (bpm), PR, QRS, QT, QTcB, QTcF

Study description

Background summary

Genital warts is a human papillomavirus (HPV)-induced non-malignant disorder affecting the genital epithelia. HPV is the most frequent sexually transmitted

viral infection. The most common HPV types causing genital warts are HPV 6 and HPV 11, which are low risk HPV genotypes.
The annual incidence of genital warts in male and female is approximately 194,5 per 100.000 in a review of the scientific literature [1]. Clinical symptoms include pruritus, burning and often patients have psychosocial problems. Genital warts are highly infectious, approximately 65% of individuals with an infected partner develop genital warts. Standard treatments are topical application of podophyllotoxin (Condyline), imiquimod (Aldara) or sinecatechines (Veregen) or surgical treatments like cryotherapy, local excision or laser treatment. With these drug treatments local irritation which can be treatment limiting is common, surgical interventions also have the associated discomfort. Even after treatment, recurrence rates of genital warts are reported to be as high as 30-50%. Recently, prophylactic vaccines were proven to offer immunity against certain HPV types and are included in the Dutch national vaccination program. However, currently no HPV vaccine is registered as therapeutic vaccine. Also the bivalent vaccine (Cervarix), used in the national vaccination program, only protects against the high risk oncogenic HPV types 16 and 18, which are not associated with genital warts. Therefore, there remains an unmet medical need for a well-tolerated topical treatment that patients can safely apply at home and a treatment which is effective in treating external genital warts.

Study objective

Primary Objectives
* To explore the pharmacodynamic effects of topically applied omiganan in patients with external genital warts
* To explore clinical efficacy of omiganan compared to placebo in patients with external genital warts.

Secondary Objective
* To assess safety and tolerability of topically applied omiganan in patients with external genital warts.

Study design

This is a phase 2, randomized, double-blind, vehicle-controlled parallel-group study. Eligible patients will be randomized in two treatment arms: 2.5% omiganan gel or vehicle, i.e. placebo, gel. The gel will be applied topically once daily for 12 weeks, with a ratio of 2:1 (active:placebo). Per subject two or more external genital warts will be treated.

Intervention

CLS001 gel 2.5% omiganan pentahydrochlorid x 12 weeks x QD

Study burden and risks

The risks associated with the topical administration of CLS001 to humans has been identified in over 2500 subjects in total in fourteen 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 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 not 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 external genital warts 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. Healthy male and female subjects * 18 years of age, with external genital warts. The health status is verified by absence of evidence of any clinical significant active or uncontrolled chronic disease other than genital warts following a detailed medical history and a complete physical examination including vital signs and 12-lead ECG. In the case of uncertain or questionable results, tests performed during screening may be repeated before randomization to confirm eligibility or judged to be clinically irrelevant for healthy subjects.
2. Clinically diagnosed and biopsy confirmed external genital warts. Subject has at least 3 external genital warts.
3. Willing to give written informed consent and willing and able to comply with the study protocol.

Exclusion criteria

Eligible subjects must meet none of the following exclusion criteria at screening:
1. Clinically significant abnormalities, as judged by the Investigator, in laboratory test results including haematology, blood chemistry panel, virology or urinalysis. In the case of uncertain or questionable results, tests performed during screening may be repeated before randomization to confirm eligibility or judged to be clinically irrelevant for healthy subjects.
2. Current clinically significant skin conditions in the anogenital area (e.g. atopic dermatitis, lichen sclerosus, lichen planus or psoriasis).
3. Pregnant, breast feeding or trying to conceive.
4. Participation in an investigational drug or device study within 3 months prior to screening or more than 4 times a year.
5. Loss or donation of blood over 500 mL within three months (males) or four months (females) prior to screening.
6. Use of active treatment (i.e. cryotherapy, laser therapy, topical medication and/or surgical treatments) for genital warts within 28 days prior to first study drug administration.
7. Immunosuppressed patients, having an immunodeficiency (primary or secondary, like HIV) or receiving immunosuppressive therapy (i.e. Transplant patients).
8. Males or Females who received a vaccination with Gardasil or Cervarix.
9. Any (medical) condition that would, in the opinion of the Investigator, potentially compromise the safety or compliance of the patient or may preclude the patient's successful completion of the clinical trial.

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	28-06-2016
Enrollment:	24
Type:	Actual

Medical products/devices used

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

Ethics review

Approved WMO Date:	25-04-2016
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	11-05-2016
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek

	(Assen)
Approved WMO Date:	06-12-2016
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	EUCTR2015-005553-13-NL
CCMO	NL56059.056.16