A phase 2, randomized, double-blind, parallel-group study to assess the pharmacodynamics, safety/tolerability and efficacy of topical omiganan in patients with usual type vulvar intraepithelial neoplasia

Published: 28-09-2015
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Primary Objective• To explore the pharmacodynamic effects of topically applied omiganan • To explore the treatment effect of omiganan compared to placebo in uVIN patients Secondary Objectives• To assess safety and tolerability • To explore the...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Vulvovaginal disorders (excl infections and inflammations)
Study type	Interventional

Summary

ID

NL-OMON42712

Source
ToetsingOnline

Brief title
Omiganan in patients with uVIN

Condition

- Vulvovaginal disorders (excl infections and inflammations)

Synonym
vulva dysplasia, vulvar intraepithelial neoplasie

Research involving

Human

Sponsors and support

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

Intervention

Keyword: pharmacodynamics, topical gel, uVIN

Outcome measures

Primary outcome

To measure the pharmacodynamic effect of topical omiganan on uVIN lesions

Secondary outcome

- To assess the safety and tolerability of Omiganan in uVIN patients

- To research the pharmacokinetics of Omiganan

Study description

Background summary

Usual type vulvar intraepithelial neoplasia (uVIN) is a human papillomavirus (HPV)-induced premalignant skin disorder affecting the vulvar skin. The incidence is increasing, especially in younger women. The majority of the affected individuals have symptoms like itching, burning, dyspareunia, and discolouration of the vulvar skin which may take on a warty appearance. Standard treatment consists of surgery or laser treatment that can be mutilating and causing physical and psychological problems. In addition, after these treatments the risk of recurrence may be as high as 40-50%. Therefore, there is need for topical treatments that women can apply at home and are effective in treating uVIN without significant toxicity and without the need for potentially mutilating surgery.
Endogenous antimicrobial peptides are critical elements of the endothelial innate immunity. In healthy skin, these peptides such as cathelicidins are induced upon colonization or other external stimuli. Omiganan is a synthetic indolicidin analogue with antimicrobial and immuno-modulatory activity that is hypothesized to effect HPV-mediated lesions on skin and other epithelia such as the vaginal mucosa. Omiganan has been shown to have inhibitory effects against

HPV and it exhibited direct inhibitory effects in IL-8, MCP-1 and IL-10 in vitro. Furthermore, immunomodulation mediated by TLRs was demonstrated since omiganan inhibited IL-10, IL-6, IL-8 and TNF-α in a concentration-dependent manner, as well as IL-1b.
CLS001 is a topical gel containing omiganan pentahydrochloride. In clinical studies completed to date (seventeen trials with various formulations) in over 2500 subjects, topical administration of omiganan appears to be safe and well tolerated. The majority of the adverse events that occurred in the clinical trials were mild and resolved without treatment.
Due to the immunomodulatory activity of omiganan and its apparent anti-viral activity, we hypothesize that omiganan is a potential new treatment for uVIN. This study is intended to assess the pharmacodynamics of omiganan as a potential treatment for uVIN. Furthermore, exploratory efficacy by means of clinical outcomes (i.e. clearance of the lesions), time to recurrence and sub-clinical parameters / biomarkers will be assessed.

Study objective

Primary Objective
• To explore the pharmacodynamic effects of topically applied omiganan
• To explore the treatment effect of omiganan compared to placebo in uVIN patients

Secondary Objectives
• To assess safety and tolerability
• To explore the pharmacokinetics of omiganan

Study design

Part 1 is a phase 2 randomized, double-blind, parallel group study. Eligible patients will be randomized in two treatment arms: topical 2.5% omiganan gel or placebo for 12 weeks, with a ratio of 8:4 respectively . Per subject one or more uVIN lesions will be treated. All patients that complete part 1 can be enrolled in Part 2 of the trial with an open label, compassionate use of topical 2.5% omiganan gel QD for up to 3 months.

Intervention

Patients will use 2.5% omiganan gel once daily on the VIN lesions

Study burden and risks

not applicable

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. Women >= 18 years
2. Biopsy proven uVIN, biopsies to have been taken within the last three months
3. Written informed consent to participate in the trial
4. At least one lesion that can be accurately measured (using RECIST criteria)
o in at least one dimension with longest diameter >= 20mm
o OR in two perpendicular dimensions that when multiplied together give a surface area of greater than 120mm2 (e.g. 15mm x 8mm or 12mm x 10mm)

Exclusion criteria

1. Has any concomitant disease or significant medical conditions 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.
2. Clinically significant abnormalities, as judged by the Investigator, in laboratory test results (including hepatic and renal panels, complete blood count, chemistry panel and urinalysis) or 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.
3. Indication of a current active infectious disease of the vulva, other than HPV
4. Pregnant, breast feeding or trying to conceive
5. Active treatment for uVIN within the previous eight weeks
6. Patients receiving immunosuppressive therapy
7. HIV positive or transplant patients
8. Any condition that in the opinion of the investigator could interfere with the conduct of the study

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):	06-11-2015
Enrollment:	12
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Omiganan Topical Gel

Generic name:	Omiganan

Ethics review

Approved WMO Date:	28-09-2015
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	15-10-2015
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	29-04-2016
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	10-05-2016
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	EUCTR2015-002724-16-NL
CCMO	NL54315.056.15