CLJI VIBLOK SAfety and perFormancE Trial

Published: 28-11-2016
Last updated: 14-04-2024

The objective of this clinical trial is to assess the safety and performance of VIBLOK in adults with HSV-2 infection by comparing virus detection in the extra-genital area before and after application of the barrier cream.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Viral infectious disorders
Study type	Interventional

Summary

ID

NL-OMON43134

Source
ToetsingOnline

Brief title
SAFE Trial

Condition

- Viral infectious disorders
- Skin and subcutaneous tissue disorders

Synonym
genital herpes, HSV-2

Research involving
Human

Sponsors and support

Primary sponsor: CLJI Worldwide
Source(s) of monetary or material Support: Industrie

Intervention

Keyword: barrier cream, Genital herpes, HSV, prevention

Outcome measures

Primary outcome

Serious Adverse Device Effect incidence during the period using VIBLOK cream.

Secondary outcome

* Comparison of HSV-2 DNA detection rate on days with asymptomatic shedding

prior and after applying VIBLOK

* Comparison of HSV-2 DNA copy number on days with asymptomatic shedding prior

and after applying VIBLOK

* Safety (Nature, frequency, duration, severity, seriousness and causality of

adverse events)

Study description

Background summary

Genital herpes has a high prevalence in industrialized as well as developing countries.
Genital herpes causes genital ulcers, increases risk for acquiring HIV infection, and may be transmitted mother to child during birth with possible serious consequences.
Medical treatments and condoms only partially reduce the risk for transmission from/ to sexual partners. Genital herpes transmission despite use of condoms is thought to be due to transfer via skin-to-skin contact in unprotected areas, and HSV-2 transmission may be enhanced by current shaving habits in the genital area leading to micro lesions (lacerations) of the skin.
VIBLOK* is a cream designed to impede the passage of viruses, such as HSV-2, across the skin. Bench and animal experiments indicate that it can block virus transmission (HIV, HPV, HSV) up to 98%.

Study objective

The objective of this clinical trial is to assess the safety and performance of VIBLOK in adults with HSV-2 infection by comparing virus detection in the extra-genital area before and after application of the barrier cream.

Study design

The VIBLOK SAfety and perFormancE Trial is a prospective, non-randomized, comparative multi-center safety and performance study. Up to 48 HSV-2 infected adults are planned to be enrolled at up to 6 participating investigational centers in The Netherlands and Germany. Participants are planned to be followed for 26-31 days, using VIBLOK for minimally 26 days in a row. Safety will be assessed by collecting all adverse events, and HSV detection will be measured from daily self-collected external genital swabs before and after application of VIBLOK.

Intervention

Please refer to the below section on study participant burden.

Study burden and risks

Risks are as follows: Unanticipated serious adverse device effects.
The burden for the study subjects is as follows:
1. for the duration of ~28 days, daily swabs before and after application of the barrier cream, marking, storing, and bring the samples to the clinic during the follow-up visit.
2. daily completion of a diary about sampling, possible herpes symptoms, and shaving and waxing habits.
3. 4 visits to the clinic: screening, inclusion/ instruction, after 14 days of sampling, and after 28 days of sampling
4. 1 follow-up phone-call with the (research) clinic: (re)-instruction study procedures, 2-5 days after start sampling
5. completion of a participants questionnaire during the last visit at the clinic.

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. Participant is male or female and at least 18 years of age
2. HSV-2 seropositive by the UW Western blot or Alegria assay
3. History of recurrent genital herpes with at least 3 recurrences in the last year or, if currently on suppressive/ prophylactic therapy, prior to starting the therapy (antiviral therapy has to be stopped at least 7 days prior to initiation of trial product).
4. General good health at the discretion of the investigator.
5. Willing to not use any topical genital therapy aside from the study drug for the duration of the trial.
6. Willing to not use any systemic anti HSV therapy during the entire study starting 7 days prior to baseline.
7. Willing to obtain 2 swabs from external-genital areas once daily for the duration of the trial.
8. Willing to keep a daily trial diary during the treatment period.
9. Negative pregnancy test for women at screening.
10. Willing to use contraceptives for the duration of the study.
11. Subject must be willing and able (in the opinion of the investigator) to understand the patient information and informed consent form and to comply with the clinical trial protocol and procedures.
12. Subject must be willing to give written informed consent.

Exclusion criteria

1. Serious medical conditions, such as diabetes, significant autoimmune disease, cancer or immunosuppression, etc. that at the discretion of the investigator will likely affect study outcomes
2. Treatment with systemic steroids or other immunomodulating agents
3. Participation in any investigational drug or device trial within 30 days prior to screening
4. Pregnancy or breastfeeding, in case of women
5. Any other conditions that in the judgment of the investigator would preclude successful completion of the clinical trial

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	27-03-2017
Enrollment:	45
Type:	Actual

Medical products/devices used

Generic name:	Barrier cream
Registration:	No

Ethics review

Approved WMO Date:	28-11-2016
Application type:	First submission
Review commission:	IRB Nijmegen: Independent Review Board Nijmegen (Wijchen)
Approved WMO Date:	07-02-2017
Application type:	Amendment
Review commission:	IRB Nijmegen: Independent Review Board Nijmegen (Wijchen)
Approved WMO Date:	24-02-2017
Application type:	Amendment
Review commission:	IRB Nijmegen: Independent Review Board Nijmegen (Wijchen)
Approved WMO Date:	23-03-2017
Application type:	Amendment
Review commission:	IRB Nijmegen: Independent Review Board Nijmegen (Wijchen)
Approved WMO Date:	21-04-2017
Application type:	Amendment
Review commission:	IRB Nijmegen: Independent Review Board Nijmegen (Wijchen)
Approved WMO Date:	31-05-2017
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
CCMO	NL58709.072.16

Study results

Date completed:	13-10-2017
Actual enrolment:	82