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Testing VERRUTOP® liquid to treat warts on the hands in children and teenagers

Submission date
04/09/2019

Recruitment status
No longer recruiting

Registration date
06/09/2019

Overall study status
Completed

Last Edited
07/10/2019

Condition category
Skin and Connective Tissue Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Warts are very common and can affect anybody. They are caused by several viruses. Palmoplantar warts (warts on the palm of the hand), especially in babies and toddlers, are a common reason for a visit to a dermatology (skin) clinic. There can be several warts in a small area, meaning that it can be too painful for the child to have them all treated at the same time by the doctor freezing them with liquid nitrogen. Nitric-zinc complex solution (NZCS) is a liquid containing nitric acid, zinc, copper and organic acids, sold as Verrutop®, that can be applied to the wart (including warts on the palm or close to the fingernail) to reduce its size painlessly. This study aims to investigate whether Verrutop® treatment is effective and tolerable in children and teenagers with warts on the palm or near the fingernail.

Who can participate?
Children over 5 years old with warts on the palm or near the fingernail.

What does the study involve?
Verrutop® is applied directly to warts using thin tube until the wart changes colour. This application is repeated, with intervals of at least 2 weeks, until the wart has disappeared or until the investigator considers that no further treatment is required.

What are the possible benefits and risks of participating?
The frequent follow-ups can benefit the participants because they are more likely to have the wart treated regularly. The Verrutop® application is only applied to the wart and not the skin around it, so the normal skin should not be damaged. Verrutop® stimulates the release of a substance called nitric oxide, which can protect against viral infection, so it is less likely that the wart will regrow. Side effects are extremely rare and occur only where the liquid has been applied.

Where is the study run from?
Hospital Universitario Son Espases (Spain)

When is the study starting and how long is it expected to run for?
January 2018 to December 2018.

Who is funding the study?
ISDIN SA (Spain)

Who is the main contact?
Javier Bustos, javier.bustos@isdin.com

Contact information

Type(s)
Public

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
ISDINTOP W1

Study information

Scientific Title
Evaluation of the application of VERRUTOP® in the treatment of palmoplantar and periungual warts in the paediatric population

Study objectives
Verrutop® is already in use in adults and children. It induces a painless caustic effect on 'difficult-to-treat' warts, including those in palmoplantar and periungual locations. However, there are few data available on this product in children and adolescents in clinical studies; therefore, the objective of the present study was to describe the efficacy and tolerability of Verrutop® in the treatment of palmoplantar and periungual warts in this population.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 27/02/2018, Comité d'Ética de la Investigació de les llles Balears (CEl-lB) (Son Espases Hospital Univeristari) , C/Crta. de Valldermossa, 79 07120 Palma Mallorca; Tel: +34 (0)871 205 000; Email: sonespases.info@ssib.es), ref: CI-214-18

Study design
Prospective and open study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Palmoplantar and periungual warts

Interventions
Verrutop® is topically applied on warts using a 30 µL capillary tube on each lesion until the wart changes color. Patients received Verrutop application every 2 weeks, until the wart was resolved or until the investigator considered that no further treatment was required. Product quantity applied is under investigator’s criteria.

Intervention Type
Device

Phase
Phase IV

Drug/device/biological/vaccine name(s)
Verrutop

Primary outcome(s)
Clearance of warts assessed by a dermatologist at the clinical site during all study visits and at the end of treatment. Complete clearance of verruca will be defined as the restoration of normal skin upon close inspection.

Key secondary outcome(s))
1. Number of sessions needed for complete disappearance of warts
2. Physician’s global satisfaction evaluation
3. Physician and patient's evaluation of esthetic results
4. Tolerability of treatment

Completion date
18/12/2018

Eligibility

Key inclusion criteria

1. Eligible patients were immunocompetent children and adolescents, with at least one palmoplantar or periungual wart suitable for topical treatment
2. Patients who had not used any other topical treatment during the previous month

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Sex
All

Total final enrolment
12

Key exclusion criteria
1. Pregnancy or lactation
2. Received previous treatments interfering with the evaluation of the warts during 30 days previous to be included in the study

Date of first enrolment
01/03/2018

Date of final enrolment
18/08/2018

Locations

Countries of recruitment
Spain

Study participating centre
Hospital Universitario Son Espases
Carretera de Valldemossa, 79,
Palma de Mallorca (Islas Baleares)
Spain
07020

Sponsor information

Organisation
ISDIN S.A.

ROR
https://ror.org/04dg86p75

Funder(s)

Funder type
Industry

Funder Name
ISDIN S.A

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and analysed during the current study will be available upon request and for no less than 5 years from Javier Bustos (javier.bustos@isdin.com). The data sets are stored on MS Excel spreadsheets and all appropriate requests for appropriate analysis and mechanisms will be considered.
Written informed consent from participants was obtained.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/12/2019	07/10/2019	Yes	No