

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

Submission date 04/09/2019	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 06/09/2019	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 07/10/2019	Condition category Skin and Connective Tissue Diseases	<input type="checkbox"/> 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

Contact name
Miss Javier Bustos

Contact details
ISDIN S.A.
Provençals 33
Barcelona
Spain
08019
+34 (0)932402020
javier.bustos@isdin.com

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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'Ètica de la Investigació de les Illes Balears (CEI-IB) (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

Secondary study design

Non randomised study

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet**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 measure

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.

Secondary outcome measures

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

Overall study start date

21/12/2017

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

Age group

Child

Sex

Both

Target number of participants

12

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.

Sponsor details
Provençals 33
Barcelona
Spain
08019
+34 (0)932402020
javier.bustos@isdin.com

Sponsor type
Industry

ROR
<https://ror.org/04dg86p75>

Funder(s)

Funder type
Industry

Funder Name
ISDIN S.A

Results and Publications

Publication and dissemination plan

The researchers intend to publish the study results in an international peer-reviewed indexed scientific journal.

Intention to publish date

01/10/2019

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