

# Clinical evaluation of the safety and effectiveness of Excilor 2-in-1 Wart Treatment in the treatment of warts on the hands and feet

<b>Submission date</b> 20/07/2022	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 27/07/2022	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 27/07/2022	<b>Condition category</b> Infections and Infestations	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Both cryotherapy (freezing) and gel treatment are proven effective and safe treatments for wart removal. They are the most commonly used treatments currently on the market and have both been studied extensively for their effectiveness and safety. Combining these treatments could achieve higher cure rates and reduce the number of applications required. The aim of this study is to evaluate the effectiveness and safety of the Excilor® 2 in 1 wart treatment in the treatment of hand and foot warts.

### Who can participate?

Adults and children (ages 4- 65 years) with warts on their hands and/or feet

### What does the study involve?

Excilor® 2 in 1 wart treatment is applied topically during a treatment cycle of 5 days (one to three treatment cycles, depending on the wart state, with a resting period of 14 days between the treatment cycles).

### What are the possible benefits and risks of participating?

Cryotherapy treatment as well as TCA wart treatment are both treatments that are used in practice by general practitioners and individuals. The risks of each treatment are known and classified as minor.

### Where is the study run from?

Medical Brands (Netherlands)

### When is the study starting and how long is it expected to run for?

October 2018 to September 2019

### Who is funding the study?

Medical Brands (Netherlands)

Who is the main contact?  
Erica Brusà, Clinical@medicalbrands.com

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Ms Erica Brusà

**Contact details**  
Piet Heinkade  
Amsterdam  
Netherlands  
1019HC  
+31 (0)20 345 5330  
Clinical@medicalbrands.com

## Additional identifiers

**Clinical Trials Information System (CTIS)**  
Nil known

**ClinicalTrials.gov (NCT)**  
Nil known

**Protocol serial number**  
18E3526

## Study information

**Scientific Title**  
Clinical evaluation of the efficacy and safety of Excilor 2-in-1 Wart Treatment in the treatment of verruca vulgaris and verruca plantaris

**Study objectives**  
The primary objective of this study was to evaluate the efficacy of Excilor® 2 in 1 wart treatment in the treatment of verruca vulgaris and verruca plantaris.

The secondary objective of this study is to evaluate the safety of Excilor® 2 in 1 wart treatment by recording the occurrence of adverse reactions.

**Ethics approval required**  
Old ethics approval format

**Ethics approval(s)**

Approved 04/12/2018, Bioethics Committee of the Regional Chamber of Physicians in Gdansk (Sniadeckich 33, 80-204 Gdansk, Poland; +48 (0)58 524 32 50; bioetyka@komisjabioetyczna.pl), ref: KB – 772 / 2018 / 04.12.2018, Protocol number #18E3526

## **Study design**

Open non-randomized before/after comparison single-centre clinical study

## **Primary study design**

Interventional

## **Study type(s)**

Treatment

## **Health condition(s) or problem(s) studied**

Verruca vulgaris and verruca plantaris

## **Interventions**

Investigational device: Excilor® 2 in 1 wart treatment

Name/code: Cryo-Active™ - Contact freezing

Galenic form: TCA-Active™ (based on Trichloroacetic Acid) – Gel

Duration 5 days per treatment cycle; a maximum of three treatment cycles

Administration route: Topical

## **Intervention Type**

Device

## **Phase**

Phase III

## **Drug/device/biological/vaccine name(s)**

Excilor® 2 in 1 wart treatment

## **Primary outcome(s)**

1. Clinical scores used to assess average wart size, swelling and softness of the wart are taken at baseline, day 19 (visit 2), day 32 or 38 (visit 3), day 51 or 57 (visit 4) and day 70 (visit 5):

1.1. Wart size measured on a scale of 0-10, 0 = absent, 10= very large

1.2. Swelling measured on a scale of 0-10, 0 = no swelling, 10= swollen wart

1.3. Wart softness measured on a scale of 0-10, 0 = soft skin on the wart, 10 = stiff skin on the wart

2. Diameter of wart measured using a calliper at baseline, day 19 (visit 2), day 32\* or 38 (visit 3), day 51\* or 57 (visit 4) and day 70\* (visit 5)

3. Change in the wart after the treatment assessed using macrophotographs taken with a Nikon D90 at baseline, day 19 (visit 2), day 32\* or 38 (visit 3), day 51\* or 57 (visit 4) and day 70\* (visit 5)

4. Impact of the wart on quality of life assessed using a Quality of Life Questionnaire (QOL) is completed at baseline, day 32\* or 38 (visit 3), day 51\* or 57 (visit 4) and day 70\* (visit 5)

5. Properties, efficacy, tolerance and future use of the studied product assessed using a subjective evaluation questionnaire filled in by the subject at day 32/38 (visit 3), day 51/57 (visit 4) and day 70 (visit 5)

\*D32 is applicable for subjects needing 1 treatment cycle; D38 is applicable for subjects needing at least 2 treatment cycles

\*\*D51 is applicable for subjects needing 2 treatment cycles; D57 is applicable for subjects needing 3 treatment cycles

\*\*\*D70 is applicable for subjects needing 3 treatment cycles

### **Key secondary outcome(s)**

Adverse events collected throughout the study course and recorded by the subjects every day in the daily log and by the investigator in the CRF at every visit

### **Completion date**

06/09/2019

## **Eligibility**

### **Key inclusion criteria**

1. Sex: female and/or male
2. Age: 45 adults 18-65 years old (inclusive) and 15 children 4-17 years old (inclusive)
3. Subjects with at least one selected wart on the hand or foot not older than 1 year and not previously treated and having a diameter of 2 to 5 mm
4. Subjects or parents/legal guardians psychologically able to understand the study-related information and to give a written informed consent
5. Subjects or parents/legal guardians have given freely and expressly their informed consent
6. Subjects or parents/legal guardians able to comply with protocol requirements, as defined in the protocol
7. Females of childbearing potential should use a medically accepted contraceptive regimen from at least 12 weeks before the beginning of the study till at least 1 month after study completion

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Mixed

### **Lower age limit**

4 years

### **Upper age limit**

65 years

### **Sex**

All

### **Total final enrolment**

66

## **Key exclusion criteria**

### **Population:**

1. Pregnant or nursing subject or planning a pregnancy during the study (females only)
2. Subject who had been deprived of her/his freedom by administrative or legal decision or who is under guardianship
3. A subject in a social or sanitary establishment
4. A subject in an emergency situation
5. A subject suspected to be non-compliant according to the investigator's judgement

### **Associated pathology:**

1. A subject having clinically significant dermatological pathologies on the tested area, according to the investigator's judgment
2. A subject suffering from a clinically significant illness, stabilized or evolutionary, according to the investigator's judgement
3. Subjects who are suffering from diabetic and/or have a poor blood circulation
4. Subjects presenting skin tags, moles, dark patches of skin, freckles, water warts (mollusca contagiosa), seborrheic keratosis (verruca seborrhoica) or exfoliated skin in the to be tested skin area
5. Damaged, open and/or inflamed skin in the treated area
6. Subjects with a known allergy or sensitivity to one of the products' components
7. Immunosuppressed subjects

### **Previous or ongoing treatment:**

1. Any treatment which, in the investigator's judgement, put the patient at undue risk or may interfere with the evaluation of the study results

### **Lifestyle:**

1. Intensive exposure to sunlight or UV-rays within the previous month and/or foreseen during or within 4-6 weeks after the study
2. A patient planning to change her/his life habits during the study (diet, cosmetic products use, sport activity etc)

## **Date of first enrolment**

01/12/2018

## **Date of final enrolment**

14/06/2019

## **Locations**

### **Countries of recruitment**

Poland

### **Study participating centre**

#### **Dermscan Poland**

ul. Kruczkowskiego 12 80-288

Gdansk

Poland

80-288

# Sponsor information

## Organisation

Medical Brands

## Funder(s)

### Funder type

Industry

### Funder Name

Medical Brands

# Results and Publications

## Individual participant data (IPD) sharing plan

In accordance with Good Clinical Practices (GCP) and the standards of the data protection law, data obtained during research involving human beings must be treated confidentially to guarantee the patients' privacy. Conforming with local regulations and ethical considerations, the sponsor representatives and/or any regulatory agency have direct access to all study records, CRFs, corresponding subject/patient medical records and any other documents considered source documentation. This data will not be made publicly available. DermScan (CRO) must archive the CIP, documentation, approvals and all other essential documents related to the study. At the end of this period (15 years), the study archives will be destroyed unless otherwise stipulated in writing by the sponsor/only when stipulated in writing by the sponsor (Medical Brands).

## IPD sharing plan summary

Not expected to be made available

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes