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

Submission date
20/07/2022

Registration date
27/07/2022

Last Edited
27/07/2022

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Infections and Infestations

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

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

Primary study design
Interventional

Study design

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

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-ActiveTM - Contact freezing
Galenic form: TCA-ActiveTM (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 f7 (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), seborrhoeic 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