PROSPECTIVE, MULTICENTRIC, BEFORE AFTER STUDY TO EVALUATE THE EFFECTIVENESS AND THE SAFETY OF A MEDICAL DEVICE IN THE TREATMENT OF COMMON WARTS AND PLANTAR WARTS

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Title of the clinical investigation:	**PROSPECTIVE MULTICENTRIC, BEFORE AFTER STUDY TO EVALUATE THE EFFECTIVENESS AND THE SAFETY OF A MEDICAL DEVICE IN THE TREATMENT OF COMMON WARTS AND PLANTAR WARTS**
Sponsor:	**PODERM Professional** Swiss Footcare Laboratories Chemin du Pré-Fleuri 1-3 1228 Plan-les-ouates SWITZERLAND
Development phase:	Exploratory study Interventional MD without CE mark
Objectives:	**Primary objective:** To evaluate the effectiveness of Sérum VERRUPRO® in the treatment of warts, assess by the evolution of the wart diameter after 35 days of treatment. **Secondary objectives**: - To evaluate the effectiveness of Sérum VERRUPRO® in the treatment of warts, assessed by the investigator , after 35 days of treatment. - To evaluate the effectiveness of Sérum VERRUPRO® in the treatment of warts assess by the investigator clinical examination, after 35 days of treatment. - To illustrate the effectiveness of Sérum VERRUPRO® on the skin aspect before and after the treatment assess by photographs. - To evaluate the patient's opinion of Sérum VERRUPRO® on the effectiveness, tolerance, and acceptability after 35 days of treatment. - To evaluate the safety and tolerance of Sérum VERRUPRO®
Design:	Prospective, multi center, before/after study.
Planned Sample Size:	33 included patients to expect result on 30 patients. 60% of patients will be treated for a wart on their back of hands or fingers. 40% of patients will be treated for a plantar wart.
Number of investigational study sites:	2 sites in Tunisia
Inclusion criteria:	1. Patient having given freely her/his informed, written consent. 2. Patient having a good general health.

	3. Age: more than 18 years. 4. Patient cooperative and aware of the device's modalities of use and the necessity and duration of the controls so that perfect adhesion to the protocol can be expected. 5. Patient being psychologically able to understand information and to give his/her consent. 6. Patient presenting at least 1 common wart, present since less than 6 months, on the fingers, back of the hands (60% of patients) and/or at least 1 plantar wart (40% of patients). 7. Patient presenting wart of a size between 0,1 and 0,5 cm. 8. Women of childbearing potential should use an accepted contraceptive regimen (at the Investigator's discretion) since at least 12 weeks before the beginning of the study and during all the study.
Exclusion criteria:	1. For plantar wart: wart on the point of support. 2. Wart with keratosis. 3. Wart in mosaic. 4. Pregnant or nursing woman or planning a pregnancy during the investigation. 5. Patient considered by the investigator likely to be non-compliant with the protocol. 6. Patient enrolled in another clinical trial during the test period. 7. Patient having a known allergy or hypersensitivity to one of the constituents of the tested products. 8. Patient with a condition or receiving a medication which, in the investigator's judgment, put the patient at undue risk. 9. Patient suffering from serious or progressive diseases (to investigator's discretion) such as uncontrolled diabetes, peripheral circulatory disease, immunocompromised patient HIV, psoriasis, lichen planus, immunosuppressive pathology, chronic venous insufficiency, Peripheral Arterial Obstructive Disease, delay or lack of unguel growth … 10. Patient with cutaneous pathology on studied zone other than warts.
Investigational device: **Name** **Galenic form** **Dosage** **Duration** **Administration route**	 Sérum VERRUPRO® Liquid solution in bottle with a brush applicator Twice daily 35 days Topical application
Endpoints:	**<u>Primary endpoint</u>** Clinical examination performed by the investigator to evaluate the diameter of the wart at D0 and 35 days after treatment. The effect of the product on clinical parameters will be evaluated by comparing the mean diameter before and after treatment. **<u>Secondary endpoints:</u>** - The global improvement of the wart will be assessed by the investigator after 35 days of treatment. - Clinical examination performed by the investigator to evaluate the roughness, thickness and the number of dermal papillae of the wart at D0 and 35 days after treatment. The effect of the product on these clinical parameters will be evaluated by a comparison before and after treatment. - Illustration of the effectiveness of Sérum VERRUPRO® on the skin aspect before and after the treatment with photographs.

	- Analysis of the answers to the patient questionnaire regarding effectiveness, tolerance, and acceptability of the investigational device 35 days after treatment. - Products safety will be assessed by collection of Adverse Events (AEs) throughout the study. AEs will be summarized and tabulated by severity, causality, action taken and outcome, using descriptive statistics. - Product tolerance will be assessed by the investigator at D0 (before the product use) and D35 by a clinical examination.
Study Procedures:	**Visit 1:** informed consent, medical interview, collection of medical history and previous treatment, checking of the inclusion and exclusion criteria, patient inclusion, selection of the studied wart, clinical examination of the wart by the investigator, tolerance parameter evaluation, preparation of the wart by the investigator (removal of the stratum corneum if needed), photography of the selected wart, application of the product by the patient, distribution of daily log and product. **Visit 2:** clinical examination by the investigator, tolerance parameter evaluation, photography of the selected wart, assessment of the global improvement by the investigator, patient subjective questionnaire, product tolerance evaluation, record of AE, concomitant treatments, study end.
Statistical methods:	The following analysis populations will be studied and will be considered for the statistical analysis: - Safety population: any patient having used the investigational device. - ITT (Intent-to-Treat): any patient included in the study with at least a post-basal value. - PP population: any patient included having used at least once the investigational device and without any major deviation to the CIP. ***Descriptive analysis:*** Quantitative data will be summarized using adapted statistics (number of values, number of missing values, mean, standard deviation, minimum and maximum values) by time point. Categorical data will be summarized in frequency (N) and percentage (%). ***Primary endpoint:*** To evaluate the effectiveness of Sérum VERRUPRO® in the treatment of warts, assessed by the evolution of the wart diameter after 35 days of treatment. Clinical examination will evaluate the diameter of the wart at D0 and 35 days after treatment. The effect of the product on clinical parameters will be evaluated by comparing the mean before and after treatment. A paired t-test will be carried out on the change from baseline outcome (D35-D0) to assess whether the mean value of the diameter of the wart decrease significantly from baseline. ***Secondary endpoints:*** - Global improvement Clinical examination of roughness, thickness and number of dermal papillae. - Subjective evaluation by the patient.

	- Tolerance by the investigator Each secondary endpoints listed above, will be summarized using adapted statistics. Safety assessment by collecting all the AEs occurred during the study will be summarized in frequency and percentage for the Safety population. Each statistical analysis test will be two tailed with a type I error set at α=0.05. **Statistical software :** SAS v9.4
Foreseen study duration:	Clinical investigation beginning: Q4 2023 Clinical investigation end: Q2 2024 Clinical investigation global duration: 4 months Duration by patient: 35 days

FLOW-CHART

Procedure	**Visit 1 Day 0**	**Visit 2 Day 35**
Days	D0	D35±7
Informed consent form signature	●	
Medical interview, medical history, previous and concomitant medications collection by the investigator	●	
Checking of the inclusion and exclusion criteria	●	
Patient inclusion	●	
Selection of the studied wart	●	
Clinical examination (diameter, roughness, thickness, dermal papillae) by the investigator	●*	●
Preparation of the selected wart (removal of the stratum corneum if needed) by the investigator	●	
Clinical examination for evaluation of product tolerance by the investigator	●*	●
Photograph of the selected wart	●* (after removal of the stratum corneum)	●
Treatment application by the patient	● (under investigator control at the site on D0 then at home)	
Patient subjective evaluation questionnaire		●
Global improvement evaluation by the investigator		●
Distribution of daily log and products	●	
AE and concomitant treatment collection	●	●
Study end		●

*Before treatment application