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Assessing the safety and effectiveness of the MDC-75 medical device for treating harmless skin growths or marks on the surface of the skin in children

Submission date
18/09/2026

Recruitment status
Not yet recruiting

Registration date
21/09/2026

Overall study status
Ongoing

Last Edited
21/09/2026

Condition category
Skin and Connective Tissue Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Harmless skin growths and marks, such as common warts, molluscum contagiosum, certain moles and skin tags, are common in children and young people. Although they are not cancer, they can sometimes cause discomfort or concern.
MDC-75 is a medical device that is applied directly to a skin growth or mark. It is designed to treat the affected tissue so that it dries out and eventually falls away. Studies in adults have suggested that MDC-75 can reduce or remove these skin growths and is generally well tolerated. However, MDC-75 has not yet been studied in children or young people.
The aim of this study is to find out whether MDC-75 is safe and works well for treating harmless skin growths and marks in children and young people.

Who can participate?
Children and young people aged 2 to 17 years can take part if they have one or more suitable harmless skin growths or marks. These include common warts, molluscum contagiosum, certain harmless moles and skin tags.
People cannot take part if, for example, the area to be treated may be cancerous or precancerous, is inflamed or damaged, or is affected by certain long-term skin conditions. There are also some other reasons why a person may not be able to take part. The study team will check whether each person is suitable before they enter the study.
The researchers plan to include 28 participants.

What does the study involve?
Participants will have MDC-75 applied directly to selected skin growths or marks by a member of the study team. The amount used will depend on the size of the area being treated and the participant's body weight.
After MDC-75 is applied, the treated skin is expected to turn white. There may also be some temporary redness around the area. The treatment may be repeated about every 10 days if the skin growth or mark has not completely disappeared. Each participant can receive up to three

applications.
Participants will visit the study centre several times. The study team will measure the skin growth or mark and take photographs to see how it changes. They will also check the skin for any reactions and ask about pain. At the end of the study, participants who are able to answer will be asked how satisfied they are with the treatment. A parent or legal guardian can answer this question when appropriate.
Participation can last for up to 13 weeks.

What are the possible benefits and risks of participating?
MDC-75 may make the treated skin growth or mark smaller or remove it completely. However, there is no guarantee that participants will benefit from taking part.
Previous studies in adults found that MDC-75 was generally well tolerated, but this is the first study in children and young people. Possible side effects include tingling, warmth or stinging shortly after treatment. Pain is possible but has been uncommon in previous studies.
The treatment may not work fully after the first application, so another application may be needed. A wound may develop, particularly if the dried skin is scratched. Other possible effects include temporary raised scarring, darkening of the skin after treatment and a delayed skin reaction to ingredients in MDC-75.

Where is the study run from?
R&D PHARMA (Monaco).

When is the study starting and how long is it expected to run for?
January 2027 to April 2027.

Who is funding the study?
R&D PHARMA (Monaco).

Who is the main contact?
Dr Gitanjali Petkar, g.petkar@cidp-cro.com

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Other number
2425CMPH135/RDP-MDC75-004

Study information

Scientific Title
Pivotal medical device class IIa study to assess the safety and performance of MDC-75 in pediatric participants with benign superficial skin lesions

Study objectives
To demonstrate the safety and clinical benefits of MDC-75 when applied to benign superficial skin lesions such as common warts, molluscum contagiosum, benign dermic naevi and acrochordons (including fibroid pendulum).

Ethics approval required
Ethics approval required

Ethics approval(s)
Not yet submitted

Primary study design
Interventional

Allocation
N/A: single arm study

Masking
Open (masking not used)

Control
Uncontrolled

Assignment
Single

Purpose
Treatment

Study type(s)

Health condition(s) or problem(s) studied
Superficial benign skin lesions among the following: common warts, molluscum contagiosum, benign dermic naevi and acrochordons (including fibroid pendulum).

Interventions
This is a prospective unicentric open label study to demonstrate the safety and clinical benefits of MDC-75 when applied to benign superficial skin lesions such as common warts, molluscum contagiosum, benign dermic naevi and acrochordons (including fibroid pendulum).
After inclusion, assessment of lesion size will be done on D1, D10, D20 and D35 and any other additional visits (if needed) , Investigator global assessment (IGA) on a 5 point scale on D10, D20 and D35 and any other
additional visits (if needed), Global assessment of improvement on a 6-point scale on D35, Participant's assessment of satisfaction on 0 to 10 NRS on D35, Image acquisition of selected lesion(s) on D1, D10, D20, D35 and any other additional visits, Frosting assessment after product application on D1, D10 (if applicable) and D20 (if applicable) or other additional visits (if needed), Pain assessment by participants/legal guardians on days when product is administered, Post inflammatory hyperpigmentation (PIH) by investigator on D35- Local tolerance of selected lesion (s) on D1, D10, D20 and D35 or any other additional visits, Application on selected lesion(s) at D1 and application repeated every 10 days (±3 days) if the entire lesion has not disappeared. Depending on the size and the location of the lesion, MDC-75 will be applied with an acid safe micropipette tip at investigator discretion until the lesion is fully and completely covered by the product.
The quantity of product applied depends on the lesion size and volume. Generally, after MDC-75 application, the skin color will change and become whitish, and the surrounding skin can show slight transient hyperaemia with mild redness.Maximum cumulative volume per patient during a single treatment session and within any 24-hour period:
For paediatric patients with bodyweight (BW) between 10 to <18 kg: Max. 10 µL MDC-75 per treatment session
For paediatric patients with BW between 18 to <30 kg: Max. 20 µL MDC-75 per treatment session
For paediatric patients with BW between 30 to <40 kg: Max. 30 µL MDC-75 per treatment session
For paediatric patients with BW between 40 to <50 kg: Max. 40 µL MDC-75 per treatment session
For paediatric patients with BW of 50 kg and above: Max. 50 µL MDC-75 per treatment session

A maximum of three applications are allowed in this CIP.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
MDC-75

Primary outcome(s)
1. Lesion size measured using a vernier caliper in terms of length, width and height (all mm) at screening, D1, D10, D20, D35 or at up to a maximum of 2 additional visits if needed

2. Severity of skin condition measured using Investigator Global Assessment (IGA) at D1, D10, D20 and D35 or any other additional visits

Key secondary outcome(s)
1. Severity of skin condition measured using global assessment of improvement (6-point scale) at D35

2. Local tolerance measured using the 5-point scale at at D10±3x, D20±3 x and D35 or on any additional visit

3. Frosting assessment measured using an adapted grading scale (Soleymani et al., 2018) at D1 or D10 or D20 or additional visits

4. Participant assessment of satisfaction and acceptability measured using questionnaire 0 to 10 NRS (children/adolescents judged to be able to complete the questionnaire)/participants' legal guardian will answer a participant assessment of satisfaction and acceptability questionnaire at D35 or earlier at exit visit in case of early discontinuation

5. Assessment of post-inflammatory hyperpigmentation (PIH) measured using 5-point IGA scale at D35 or earlier at exit visit in case of early discontinuation

6. Pain assessment measured using pain scales adapted to age of participants will be used to evaluate pain at D1, D10, D20 or any additional

Completion date
26/04/2027

Eligibility

Key inclusion criteria
1. Male or female participants aged 2-17 years
2. Participants with one or several clinically typical benign skin lesions among the following: common warts, molluscum contagiosum, benign dermic naevi* and acrochordons* (including fibroid pendulum)
3. Participant of any phototype (according to Fitzpatrick scale)

Healthy volunteers allowed
Yes

Age group
Child

Lower age limit
2 Years

Upper age limit
17 Years

Sex
All

Total final enrolment
28

Key exclusion criteria
1. Participants with atypical skin lesions or skin lesions suspected to be a precancerous lesion or a skin cancer
2. Target lesion is a melanocytic epidermal nevus or any atypical nevi
3. Target lesion is a flat or mosaic type warts
4. Target lesion located on a skin area affected by a chronic disease that might interfere with the evaluation or might be worsened by the test procedure (such as but not limited to atopic dermatitis, psoriasis, vitiligo)
5. Target lesion shows inflammation, ischemia or necrosis
6. Target lesion located on a skin area treated with a topical medication
7. Participant having a history of keloid, hypertrophic scar or any abnormal scarring
8. Participant with multiple post-inflammatory hyperpigmented lesions
9. Participant not willing to comply with the photoprotection measures related to the treated area
10. Participant who is pregnant or breastfeeding or considering a pregnancy during the study
11. Female participants of childbearing potential with a positive urine pregnancy test at baseline

Date of first enrolment
25/01/2027

Date of final enrolment
22/03/2027

Locations

Countries of recruitment
Mauritius

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Sponsor information

Organisation
R&D PHARMA

Funder(s)

Funder type

Funder Name
R&D PHARMA

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available