ISRCTN16760053 https://doi.org/10.1186/ISRCTN16760053

To confirm the safety and performance of MDC-75 in individuals with benign superficial skin lesions

Submission date
25/06/2025

Recruitment status
No longer recruiting

Registration date
30/06/2025

Overall study status
Completed

Last Edited
24/10/2025

Condition category
Skin and Connective Tissue Diseases

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

Plain English summary of protocol

Background and study aims
Benign superficial skin lesions, such as seborrheic keratoses, actinic keratoses, and fibroid pendulum, are a common concern for millions globally. Although these lesions are generally non-life-threatening, they can cause discomfort, aesthetic issues, and sometimes require medical intervention. Current treatments like cryotherapy, laser therapy, and surgical excision are effective but can lead to patient discomfort, scarring, or less-than-ideal cosmetic results. Topical agents have gained attention as non-invasive, patient-friendly alternatives or complements to traditional treatments. These agents offer precise application, minimize procedural risks, and improve patient compliance. However, the effectiveness of existing topical treatments varies, and many are limited by tolerability issues, highlighting the need for more targeted and effective formulations.
The destruction of small skin lesions by tissue denaturation (fixation) rather than erosion (acid hydrolysis) has long been proposed for isolated benign lesions. This procedure (as opposed to chemocautery with strong acids) has the advantage of being simple, controllable, and essentially painless. The treated tissue becomes fixed in situ and the devitalized lesion falls away in a desiccated form (mummified) after several days, but still retains its architecture, so that histopathologic diagnosis is possible if needed. This approach has been used for the treatment of a variety of benign skin lesions, including solar keratosis, verrucae, condyloma acuminata, hemangiomas and papillomas. Several products sharing this mechanism of action reached the market, including Solcoderm, Zeroverrue or Verrutop. They were generally developed as medical devices.
R&D Pharma has developed MDC-75 for the treatment of benign superficial skin lesions. The safety and efficacy of this product were first investigated in a model of DMBA/TPA-induced papillomas in balb/c mice. Following induction of skin tumors using the mutagen DMBA (single application) and the oncogenesis activator TPA (twice weekly for 17 weeks), 40 Balb/c mice (10 per group) were treated with one of the following test treatments: MDC-75 (same formulation as intended in the proposed study), MDC-75 with luminol, the marketed reference product Solcoderm® or Placebo. MDC-75 was very well tolerated, at either clinical examination (no systemic effects, no local signs) or histopathological evaluation of the treated sites (i.e. no skin hyperplasia, dysplasia or fibrosis). MDC-75 demonstrated a high effectiveness, whatever the

lesion characteristic (size or presence of ulcers) with a single application being enough to cure tumors in most animals. The mean time for complete rejection of mummified scab was 3 to 4 days and the mean time for complete healing after rejection was 9 to 12 days. There was no efficacy difference between active treatment groups.
MDC-75 (same formulation as intended in the proposed study) was used to treat benign skin lesions in 5 patients (34 to 74 years of age). Safety appears good with only limited transient tingling and warm sensation and no burn of healthy skin surrounding the treated lesion. Efficacy evaluation reported a complete cure of the treated lesions without scarring and no relapse after several years of follow-up. Four patients out of five received two applications of the test treatment to achieve this result. Lesions were mummified and fully rejected within 8 to 38 days. Complete cure after detachment of the mummified lesion was achieved in 5 to 9 weeks. No post-inflammatory hyperpigmentation and no scar were observed.
Finally, a clinical study was conducted to confirm the good local tolerance and assess the efficacy of MDC-75 in five types of benign skin lesions: acrochordons, common warts, benign dermic naevi, seborrheic keratoses, and actinic keratoses. In this study, MDC-75 was applied to one or several lesions with the application being repeated every 15 days if the lesion was still present. A maximum of three applications were planned in the protocol.
The aim of this study is to confirm the safety and performance of MDC-75 in individuals with benign superficial skin lesions.

Who can participate?
Healthy volunteers regardless of gender, aged at least 18 years, who do not meet contraindications for the topical treatment of superficial benign skin lesions among the following: seborrheic keratosis, common warts, benign dermic naevi, acrochordons (including fibroid pendulum), or isolated low-grade actinic keratosis.

What does the study involve?
This is a prospective unicentric open-label study to demonstrate the safety and clinical benefits of MDC-75 when applied to isolated low-grade actinic keratoses or benign superficial skin lesions such as seborrheic keratoses or fibroid pendulum. The study will last a total of a maximum of 12 weeks with visits to the investigation center every 10 days.

What are the possible benefits and risks of participating?
The destruction of small skin lesions by tissue denaturation (fixation) rather than erosion (acid hydrolysis) has long been proposed for isolated benign lesions. This procedure (as opposed to chemocautery with strong acids) has the advantage of being simple, controllable, and essentially painless. The treated tissue becomes fixed and the devitalized lesion falls away in a desiccated form (mummified) after several days, but still retains its architecture, so that histopathologic diagnosis is possible if needed. This approach has been used for the treatment of a variety of benign skin lesions, including solar keratosis, verrucae, condyloma acuminata, hemangiomas and papillomas.
MDC-75 acts on the destruction of small skin lesions by tissue denaturation rather than erosion. It does not breach the dermis significantly.
Possible benefits include a reduction in lesion size and complete cure.
Topical administration of MDC-75 is generally well-tolerated, and most side effects are mild in intensity and transient in nature. They are related to the investigational device.
The most frequent adverse events associated with topical application include:
1. Instantaneous: tingling, burning sensation
2. Short-term: inflammation (limited to the lesion) up to 15 days after application
3. Longer term: hypertrophic scarring, post-inflammatory hyperpigmentation

Where is the study run from?
CIDP Ltée (Mauritius)

When is the study starting and how long is it expected to run for?
September 2025 to November 2025

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

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

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Dr Gitanjali Petkar

Contact details
Biopark
Socota Phoenicia
Sayed Hossen Road
Phoenix
Mauritius
73408
+230 (0)59456780
g.petkar@cidp-cro.com

Additional identifiers

Protocol serial number
2425CMPH206

Study information

Scientific Title
Pivotal medical device class IIA study to assess the safety and performance of MDC-75 on subjects with benign superficial skin lesions

Study objectives
1. Safety-wise, this study builds on the hypothesis that MDC-75 does not significantly induce local intolerances and adverse events following application. Thus, the null hypothesis (to be rejected) is that MDC-75 causes local intolerances and adverse events.
2. Performance-wise, the null hypothesis (to be rejected) is that there is no difference between before and after evaluations in terms of lesion size, IGA and other derived parameters. The alternative hypothesis is that there is an improvement at post-baseline assessments in terms of the mean/median scores

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 17/09/2025, Clinical Research Regulatory Council (Level 2, Nexsky Building, Ebene, 72201, Mauritius; +230 (0)5942 0845; crrc@govmu.org), ref: 2425CMPH206

Primary study design
Interventional

Study design
Prospective unicentric open-label study

Study type(s)
Efficacy, Safety

Health condition(s) or problem(s) studied
Superficial benign skin lesions: seborrheic keratosis, common warts, benign dermic naevi, acrochordons (including fibroid pendulum), or isolated low-grade actinic keratosis

Interventions
This is a prospective unicentric open-label study to demonstrate the safety and clinical benefits of MDC-75 when applied to isolated low-grade actinic keratoses or benign superficial skin lesions such as seborrheic keratoses or fibroid pendulum.

After inclusion:
1. Assessment of lesion size will be done on D1, D10, D20 and D35 and any other additional visits if needed
2. Investigator global assessment (IGA) on a 5-point scale on D1, D10, D20 and D35 and any other additional visits if needed
3. Global assessment of improvement on a 6-point scale on D35
4. Subject's assessment of satisfaction on a 0 to 10 Numerical Rating Scale (NRS) on D35
5. Image acquisition of selected lesion(S) on D1, D10, D20, D35 and and any other additional visits if needed
6. Pain assessment by subjects on days when the product is administered
7. Post-inflammatory hyperpigmentation (PIH) by investigator on D35
8. 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 is applied with a micropipette tip or with a cotton bud 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.

A maximum of three applications is 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 vernier caliper on D0, D10, D20 and D35 or any other additional visits
2. Investigator global assessment (IGA) on a 5-point scale on D0, D10, D20 and D35 or any other additional visits
3. Global assessment of improvement on a 6-point scale on D35
4. Subject’s assessment of satisfaction on a 0 to 10 NRS on D35

Key secondary outcome(s)
Local tolerance and safety measured using 5-point scale at D0, D10, D20 and D35 or any other additional visits

Completion date
17/11/2025

Eligibility

Key inclusion criteria
1. Subjects aged at least 18 years old
2. Subjects with one or two clinically typical benign skin lesions among the following: seborrheic keratosis, common warts, benign dermic naevi, acrochordons (including fibroid pendulum), or subjects with isolated low-grade actinic keratosis
3. Subject of any phototype (according to Fitzpatrick scale)
4. Subject understanding and accepting the constraints of the CIP
5. Subject who has signed their informed consent for their participation in the study and a photograph authorization
6. Subject able to understand the language used in the investigational centre and the information given
7. Cooperative subject, aware of the necessity and duration of controls so that perfect adhesion to the CIP established by the investigational centre could be expected (able to comply with the CIP and follow CIP’s constraints and specific requirements)
8. Females of childbearing potential committing themselves to use an effective contraceptive method through the study and for at least 3 months before the inclusion visit (with no change during this period)

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Subjects 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 wart
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. Subject having a history of keloid, hypertrophic scar or any abnormal scarring
8. Subject with multiple post-inflammatory hyperpigmented lesions
9. Subject not willing to comply with the photoprotection measures related to the treated area
10. Subject who is pregnant or breastfeeding or considering a pregnancy during the study
11. Female subjects of childbearing potential with a positive urine pregnancy test at baseline
12. Subject who has been deprived of their freedom by administrative or legal decision or who is under guardianship
13. Subject who cannot be contacted by telephone in case of emergency
14. Subject in an exclusion period or participating in another biomedical research study (self-reported)
15. Intellectual/mental inability to follow study instructions (if suspected) or incapacitation
16. Subjects working for the contract research organization (CIDP) in charge of this study

Date of first enrolment
22/09/2025

Date of final enrolment
13/10/2025

Locations

Countries of recruitment
Mauritius

Study participating centre
CIDP Ltée
Biopark
Socota Phoenicia
Sayed Hossen Road
Phoenix

Mauritius
73408

Sponsor information

Organisation
R&D Pharma

Funder(s)

Funder type
Industry

Funder Name
R&D Pharma

Results and Publications

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date