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A clinical research study to evaluate the safety and tolerability of a topically applied investigational drug product in adults with vitiligo and to evaluate if it helps in restoring the pigment/color to the affected skin

Submission date
15/10/2024

Recruitment status
Recruiting

Registration date
30/10/2024

Overall study status
Ongoing

Last Edited
30/10/2024

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
Vitiligo, a skin disorder characterized by the loss of pigment, can significantly impact the affected individual's mental well-being, social interactions, and quality of life due to its visible nature and associated stigma. This study involves a new topical skin treatment called VIM-004 Gel, which combines afamelanotide, a known medication that increases the pigmentation of the skin with STAR particles, a medical device used for creating micropores across the top layers of the skin to allow the delivery of afamelanotide, that otherwise would not penetrate the skin. VIM-004 Gel aims to help repigment the skin areas affected by vitiligo.

Who can participate?
Adult patients aged between 18-70 years old with vitiligo

What does the study involve?
Participants must pass a clinical evaluation including lab tests and a physical examination to confirm eligibility to participate. Two skin areas affected by vitiligo will be selected for each participant. Except for the areas located in the face, these areas should include between 10-20% of pigmented skin. Participants will receive NB-UVB 3 times/week for 30 days during a pre-treatment phase. The investigational product (VIM-004 Gel) will then be applied to one area 5 times/week for 12 weeks, while a placebo (which is the gel with STAR particles, but without afamelanotide) will be applied to the other. Participants will continue to receive NB-UVB treatment 3 times/week during the treatment phase. Please note that not all areas affected by vitiligo will receive treatment. Participants will be regularly evaluated for safety and tolerability of the drug product, blood samples will be collected periodically and skin images will be collected throughout the treatment period to evaluate response to treatment. Skin biopsies will be performed in a subset of participants.

What are the possible benefits and risks of participating?
Participants may see repigmentation of the treated skin lesion. However, it is not known if taking part in this study will help your condition stay the same or worsen. As part of the study, your health will be closely monitored by qualified doctors. Nevertheless, even if there is no guarantee that you will have a personal medical benefit from taking part in this clinical study, the information obtained may help to better treat people with your condition.

Afamelanotide administered as a subcutaneous implant is associated with plasma exposure and side effects such as nausea, headache, fatigue and hypersensitivity reactions. In addition, systemic exposure to afamelanotide has been shown to induce skin hyperpigmentation of non-lesional skin in vitiligo patients. In this study, VIM-004 Gel will be applied on restricted areas of the skin, so the amount of the active ingredient expected to reach the bloodstream is anticipated to be minimal, and the blood levels at which these side effects occur are unlikely to be reached. You may experience an increase in pigmentation in the application area. In addition, when applied on the skin, there is a possible risk of local skin reactions, including erythema, oedema, and/or bleeding, associated with the mechanical mode of action of the STAR particles. When VIM-004 Gel is applied on the face there is a potential risk of translocation of STAR particles to the eyes and the mouth. There may be side effects from the investigational product that are not known at this time.

Where is the study run from?
The study is being conducted by Centre International de Développement Pharmaceutique, Mauritius

When is the study starting and how long is it expected to run for?
August 2024 to May 2026

Who is funding the study?
Vimela Therapeutics, Ltd

Who is the main contact?
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
VIM-004 Gel-01/ 2324CMPH078

Study information

Scientific Title

A phase Ib/IIa, proof of concept, double-blind, placebo-controlled, intraindividual randomized study to evaluate the safety, tolerability, and preliminary efficacy of VIM-004 gel in participants with vitiligo

Study objectives
1. VIM-004 Gel is safe and well tolerated.
2. Topical application of VIM-004 Gel has minimal to no systemic exposure.
3. VIM-004 Gel + NB-UVB treatment repigments vitiligo lesions more than NB-UVB treatment + VIM-004 Placebo Gel.

Ethics approval required
Ethics approval required

Ethics approval(s)
Submitted 30/10/2024, Clinical Research Regulatory Council (2nd Floor, Bacha Building Right Wing, Cathedral Square, Port Louis, -, Mauritius; -; not@provided.com), ref: 2324CMPH078

Study design
Single-center double-blind placebo-controlled intraindividual randomized study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Pharmaceutical testing facility

Study type(s)
Safety, Efficacy

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Vitiligo

Interventions
All eligible participants will be randomized using the randomization list provided by an unblinded statistician. The randomization list will define the treatment (VIM-004 Gel or VIM-004 Placebo Gel) to be allocated to each treatment area (Area 1 and Area 2) per participant (intra-individually). The pre-defined list will ensure that treatment assignment is unbiased, and this will be concealed from participants and blinded site staff. The randomization schedule will be produced by the unblinded staff using SAS 9.4. The unblinded statistician will not take part in any of the study-related processes.

Two application areas between 9-25 cm2 will be defined. Participants will start with a narrow-band (NB)-UVB pretreatment period for 30 days in all application areas. These areas will be randomised in a 1:1 ratio on Day 1 to VIM-004 Gel and VIM-004 Placebo Gel, with NB-UVB

treatment. VIM-004 Gel or VIM-004 Placebo Gel will be applied topically once a day on the 2 application areas. The application will be repeated for a total of 5 consecutive days per week for 12 weeks. During the treatment period, all application areas will also receive NB-UVB treatment 3 times per week. There will be a 4-week follow-up period.

Intervention Type
Drug

Pharmaceutical study type(s)
Pharmacokinetic

Phase
Phase I/II

Drug/device/biological/vaccine name(s)
VIM-004 Gel

Primary outcome measure
Safety and tolerability will be assessed by:
1. Local tolerability assessment measured using a dermal response scale, sensation scale, and pain Numeric Rating Scale (NRS) and evaluating adverse events during all study visits during the treatment period
2. Recording vital signs and performing physical examinations weekly throughout the 12-week treatment period and at 4 weeks post-treatment
3. Evaluating clinical laboratory results at week 6 during the treatment period and at 4 weeks post-treatment.

Secondary outcome measures
1. Plasma concentration of VIM-004 measured using pharmacokinetic methods on Day 1, Day 8 and Week 12

Exploratory outcome measures:
1. Repigmentation measured using planimetry and image analysis weekly
2. Repigmentation percentage for target lesions measured using the Vitiligo Extent Score for a Target Area (VESTA) weekly

Overall study start date
12/08/2024

Completion date
30/04/2026

Eligibility

Key inclusion criteria
1. Aged 18 to 70 years
2. Clinical diagnosis of stable nonsegmental vitiligo lesions
3. Fitzpatrick's skin phototype of >=4
4. Has nonsegmental vitiligo lesions that can accommodate 2 application areas between 9-25 cm2 of comparable VESTA score in easy-to-treat areas

5. Has nonsegmental vitiligo lesions with a maximum of 10% white hairs in the 2 selected application areas
6. Females of childbearing potential must have a negative serum pregnancy test at screening and a negative urine pregnancy test on Day 1
7. Involved in sexual intercourse that could lead to pregnancy: must agree to use a highly effective contraceptive method from >= 4 weeks prior to the pretreatment period and until >=2 weeks after the last study product application
7. Willing to participate and is capable of giving informed consent
8. Willing and able to comply with all study procedures and must be available for the duration of the study

Participant type(s)
Patient

Age group
Mixed

Lower age limit
18 Years

Upper age limit
70 Years

Sex
Both

Target number of participants
25

Key exclusion criteria
1. Has active form(s) of inflammatory skin disease or evidence of skin condition that would interfere with evaluation of vitiligo or response to treatment
2. Has active acute or chronic skin infection requiring treatment with systemic antibiotics, antivirals, antiparasitics, antiprotozoals or antifungals within 2 weeks prior to Day 1 or superficial skin infections within 1 week prior to Day 1
3. Has the presence of any tattoos, scratches, open sores, excessive hair, or skin damage in the application areas
4. Has active forms of other hypopigmentation
5. Is a female who is breastfeeding, pregnant, or who is planning to become pregnant during the time of the study
6. Is known to have immune deficiency or is immunocompromised.
7. Has a history of cancer or lymphoproliferative disease within 5 years prior to Day 1
8. Had a major surgery within 8 weeks prior to Day 1 or had a major surgery planned during the study
9. Has any clinically significant medical condition or physical/laboratory/vital signs abnormality that would put the participant at undue risk or interfere with the interpretation of study results
10. Has a positive result for hepatitis B virus, hepatitis C virus, or human immunodeficiency virus
11. Has used permanent depigmentation treatment for vitiligo and/or other types of pigmentation disorders at any time
12. Has used systemic treatments that could affect vitiligo within 8 weeks prior to the pretreatment period or within 5 half-lives, whichever is longer

13. Has used topical medicated treatment that could affect vitiligo
14. Has used herbal medications with unknown properties or known beneficial effects for vitiligo within 1 week of the pretreatment period
15. Has received any marketed or investigational biological agent within 12 weeks or 5 half-lives (whichever is longer) prior to the pretreatment period
16. Is currently receiving a nonbiological investigational product or device or has received one within 4 weeks prior to the pretreatment period
17. Has received any ultraviolet (UV)-B phototherapy, has had psoralen-UV-A (PUVA) treatment, or excimer laser within 4 weeks prior to the pretreatment period
18. Use of any prior and concomitant therapy not listed above that may interfere with the objective of the study as per the discretion of the investigator, including drugs that cause photosensitivity in the UVB range or skin pigmentation (eg, antibiotics such as tetracyclines, antifungals) within 8 weeks of screening
19. Has had excessive sun exposure, is planning outdoor activities with long-hours exposure to the sun, has used tanning booths within 4 weeks prior to the pretreatment period or is not willing to minimize natural and artificial sunlight exposure during the study
20. Has a known history of clinically significant drug or alcohol abuse in the last year prior to the pretreatment period
21. Has a known or suspected allergy to the active ingredient (afamelanotide) in VIM-004 Gel or any other component of the investigational medicinal product.
22. Is institutionalized because of legal or regulatory order
23. Has a history of an allergic reaction or significant sensitivity to lidocaine or other local anesthetics and latex

Date of first enrolment
15/01/2025

Date of final enrolment
15/08/2025

Locations

Countries of recruitment
Mauritius

Study participating centre
Centre International de Developpement Pharmaceutique
BioPark Mauritius, Socota Phoenicia, Sayed Hossen Road
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Sponsor type
Industry

Funder(s)

Funder type
Industry

Funder Name
Vimela Therapeutics, Ltd.

Results and Publications

Publication and dissemination plan
Planned publication in a peer-reviewed journal

Intention to publish date
30/04/2027

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