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Efficacy and safety of a topical test product in adults with vitiligo (a long-term skin condition that results in pale white patches on the skin)

Submission date
14/11/2025

Recruitment status
Not yet recruiting

Registration date
17/11/2025

Overall study status
Ongoing

Last Edited
14/11/2025

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 is a chronic, acquired depigmenting disorder of the skin characterized by the selective destruction of melanocytes, leading to well-demarcated white patches.
This study aims to evaluate the therapeutic efficacy of the test product in non-segmental vitiligo (NSV), with specific focus on the extent of repigmentation, stabilization of disease progression, and improvement in patient-reported outcomes.

Who can participate?
Male and female between 18 and 65 years old with Fitzpatrick phototype III to V having non-segmental vitiligo.

What does the study involve?
Subjects are randomly allocated to apply on the vitiligo patches either the test product, or the placebo or the tacrolimus ointment 0.1%. Vitiligo patches are evaluated at baseline, week 6, week 12, week 18 and week 24.

What are the possible benefits and risks of participating?
The possible benefits are the repigmentation of vitiligo patches, stabilization of disease progression and improvement in patient-reported outcomes.
The test product contains ingredients approved for cosmetic usage and is found to be safe to be used on human skin.

Where is the study run from?
MS clinical research, Bangalore, India

When is the study starting and how long is it expected to run for?
Enrolment: 20 December 2025 till 6 April 2026, study expected completion date : October 2026

Who is funding the study?
ISISPHARMA (France)

Who is the main contact?
Joëlle AL CHOBOQ (ISISPHARMA), jalchoboq@isispharma.com

Contact information

Type(s)
Principal investigator

Contact name
Dr Mukta Sachdev

Contact details
MS Clinical Research Pvt. Ltd
327/15 1st main road cambridge layout Ulsoor
Bangalore
India
560008
+ 91 9845044066
mukta.sachdev@msclinical.com

Type(s)
Scientific

Contact name
None Ritambhara -

Contact details
MS Clinical Research Pvt. Ltd
327/15 1st main road cambridge layout Ulsoor
Bangalore
India
560008
+ 91 9945952952
ritambhara@msclinical.com

Type(s)
Public

Contact name
None Soniya Wills

Contact details
MS Clinical Research Pvt. Ltd
327/15 1st main road cambridge layout Ulsoor
Bangalore
India
560008
+ 91 9759593715
soniya@msclinical.com

Type(s)
Scientific

Contact name
Dr Joëlle AL CHOBOQ

Contact details
ISISPHARMA, 78 rue de la villette
Lyon
France
69003
+33 4 28 00 05 86
jalchoboq@isispharma.com

Additional identifiers

Study information

Scientific Title
A randomized, double-blind, placebo-controlled, multicentred study to evaluate the efficacy and safety of a topical test product in trial participants with non-segmental vitiligo

Study objectives
Test product is effective and safe for vitiligo

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 29/10/2025, ACE independent ethics committee (2nd floor B portion, Nandanam Building, No. 1, B Channasandra, OMBR 5th Main Road, Bangalore, 560043, India; + 91 63619 87546; aceiec13@gmail.com), ref: SKIN/IPVT/2025-01

Study design
Multicenter interventional double-blinded randomized controlled trial

Primary study design
Interventional

Study type(s)
Efficacy, Quality of life, Safety

Health condition(s) or problem(s) studied
Non-segmental vitiligo

Interventions
Participants are randomized into 3 arms:
Arm 1: Topical test product (A thin layer should be applied twice daily morning and evening). The layer should completely cover the depigmented patches extending beyond the border.
Arm 2: Placebo (A thin layer should be applied twice daily morning and evening). The layer

should completely cover the depigmented patches extending beyond the border.
Arm 3: Standard treatment, tacrolimus ointment 0.1% (A thin layer should be applied twice daily morning and evening). The layer should completely cover the depigmented patches extending beyond the border.

For all study arms, the total duration of the treatment is 24 weeks with weekly follow-ups.
Randomisation process: Computer generated randomisation.

Intervention Type
Other

Primary outcome(s)
1. Degree of re-pigmentation in vitiligo-affected areas measured using dermatological, instrumental, and photographic evaluations using Vitiligo Area Scoring Index (VASI) at baseline, Week 6, week 12, week 18, week 24

Key secondary outcome(s))
1. Dermatological examination, instrumental measurements, and standardized photographic evaluation using VETF scores at baseline, Week 6, week 12, week 18, week 24
2. % repigmentation, using VASI, and VETF changes at baseline, Week 6, week 12, week 18, week 24
3. Safety and tolerability of test product over the treatment period at baseline, Week 6, week 12, week 18, week 24

Completion date
31/10/2026

Eligibility

Key inclusion criteria
1. Male & female trial participants in general good health.
2. Trial participants in the age group of 18-65 years (both ages inclusive).
3. Trial participants with Fitzpatrick phototypes III to V.
5. Participant has not received phototherapy within the past 3 months, has not used any topical vitiligo treatment within the past 4 weeks, and is not currently undergoing any vitiligo treatment prior to the Screening Visit.
6. Trial participants free of excessive hair, acne, cuts, abrasions, fissures, wounds, lacerations, or any other active skin conditions on the test sites as determined by the dermatologist.
7. Trial participants who agree not to use any other product/treatment/home remedies except the provided products during the study period.
8. Trial participants who agree not to initiate any new dietary supplements, herbal products, or over-the-counter medications targeting skin pigmentation during the study period.
9. Trial participants agree to not change their normal hygiene and cleansing routine such as increasing or decreasing shower frequency or changing the soap or cleanser they have been using safely for the 30 days prior to enrolment.
10. Trial participants willing to avoid direct sun exposure (Use umbrella, Cap, Hat if stepping out in direct sunlight).
11. Trial participants who agree not to carry out bleaching or any other cosmetic/dermatologic procedures (including facials, chemical peels, or laser treatments) during the study period.
12. Trial participants willing to give a voluntary written informed consent, photography release and agree to come for regular follow-up.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
65 years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Trial participant with any other signs of significant local irritation or skin disease at or near the target area.
2. Trial participant currently taking any medication, which the Investigator believes may influence the study outcomes.
3. Trial participant having clinically significant systemic or cutaneous disease, chronic illness or had major surgery in the last year.
4. Trial participants unwilling to discontinue other topical products for the study duration.
5. Trial participant allergic or sensitive to bar, cleansing products, cosmetics, creams/lotions, artificial jewellery or anything else.
6. Trial participants who are pregnant and lactating (self-declared).
7. Trial participants who are currently under/planning to start hormone replacement therapies (HRT) or hormonal birth control less than 3 months prior to the study entry.
8. Any condition or circumstance that, in the opinion of the investigator, would interfere with the participant’s ability to comply with the study protocol.
9. Trial participants who are an employee of sponsor or CRO.

Date of first enrolment
20/12/2025

Date of final enrolment
30/03/2026

Locations

Countries of recruitment
India

Study participating centre
MS Clinical Research Pvt. Ltd
Department of Skin Sciences, #324, Second Floor, 1st Main Road, Cambridge Layout, Ulsoor 36-1, Second Floor, 1st Main Road, Cambridge Layout, Ulsoor
Bangalore
India
560008

Sponsor information

Organisation
ISISPHARMA

Funder(s)

Funder type
Not defined

Funder Name
ISISPHARMA

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available