ISRCTN98144507 https://doi.org/10.1186/ISRCTN98144507

A study evaluating the safety and effectiveness of STIM+ injections to restore lost cheek volume in adults

Submission date
05/08/2026

Recruitment status
Not yet recruiting

Registration date
14/08/2026

Overall study status
Ongoing

Last Edited
12/08/2026

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
As people age, they may lose volume in their cheeks, making their face appear flatter and less defined. STIM+ is a new injectable medical device designed to restore lost cheek volume and improve facial appearance. This study aims to evaluate how safe and effective STIM+ is for treating loss of cheek volume and to assess how long any improvements last over a 1-year period.

Who can participate?
Adults (male and female) aged 30 to 70 years who have moderate to significant loss of cheek volume and who are seeking aesthetic treatment may be eligible to participate. Participants must be in good health and willing to attend all study visits. Pregnant or breastfeeding women, and individuals with certain medical conditions or recent facial aesthetic treatments, will not be eligible to participate.

What does the study involve?
A total of 75 participants will be enrolled and treated, and at least 60 are evaluable for the primary endpoint. Participants who meet the study requirements will receive a single treatment with STIM+ injections in both cheeks to help restore lost cheek volume.
Participants will attend follow-up visits for 4 weeks, 26 weeks, and 52 weeks after treatment. During these visits, the investigators will assess changes in cheek volume, skin texture, skin firmness, and overall facial appearance using clinical assessment gradings, photographs, and specialized skin measurement devices. Participants will also complete questionnaires about their satisfaction with the treatment and report on any side effects they may experience.

What are the possible benefits and risks of participating?
Participants may experience improved cheek volume and facial appearance.
The most common side effects are temporary redness, swelling, bruising, tenderness, itching, firmness, or warmth at the injection site. Less common side effects include uneven results, small lumps under the skin, or prolonged inflammation. Rare but serious complications include infection, allergic reactions, injury to blood vessels, tissue damage, or vision-related

complications associated with facial injections. All injections will be administered by trained physicians, and participants will be closely monitored throughout the study.

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

When is the study starting and how long is it expected to run for?
November 2026 to March 2028

Who is funding the study?
Louna Aesthetics (France)

Who is the main contact?
Bhavna Sewnundun, b.sewnundun@cidp-cro.com

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Additional identifiers

Study information

Scientific Title
Clinical investigation evaluating the safety and effectiveness of STIM+ injectable medical device in the treatment of midface volume deficit

Study objectives
Primary objective:
The primary endpoint is to evaluate the effectiveness of STIM+ in the correction of midface (cheek) volume deficit at 4 weeks post-injection, as assessed by the investigator using the Global Aesthetic Improvement Scale (GAIS).

Secondary objective:
The secondary objectives of the study are:
1. To assess improvement in:
1.1. Midface volume deficit using the Allergan Cheek Volume Scale
1.2. Skin texture (roughness) using Antera 3D
1.3. Skin firmness and elasticity using Cutometer® measurements
at visit D-3 – D0/baseline (D0) pre-injection, 4 weeks (D28), 26 weeks (D182), and 52 weeks (D364) post-injection.
2. To assess aesthetic improvement using the Global Aesthetic Improvement Scale (GAIS) as evaluated by both the investigator and the participant at 4, 26, and 52 weeks post-injection.

3. To assess injector satisfaction with injection quality using a participative questionnaire.
4. To illustrate the treatment effect of the product through 2D photography and a ¾ angle.
5. To assess safety by monitoring injection site reactions, including signs of irritation or sensitivity, using questionnaires completed by both the investigator and the participant throughout the study.
6. To evaluate participant satisfaction with treatment outcomes using a participative questionnaire at 4 weeks (D28), 26 weeks (D182), and 52 weeks (D364) post-injection.
Additionally, standardized photography will be made for the purpose of efficacy illustration, subsequently image-analyzed and scored by independent assessors for various features including mid-face volume deficit

Ethics approval required
Ethics approval required

Ethics approval(s)
Submitted 05/08/2026, Clinical Research Regulatory Council and Ethics Committee (Centre International de Développement Pharmaceutique (CIDP) Ltée Level 2 Nexsky Building, Ebene, 72201, Mauritius; +230 (0)460 4200; crrc@govmu.org), ref: 2526CMPH224

Primary study design
Interventional

Allocation
N/A: single arm study

Masking
Open (masking not used)

Control
Uncontrolled

Assignment
Single

Purpose
Device feasibility, Treatment

Study type(s)

Health condition(s) or problem(s) studied
Midface volume deficit

Interventions
The design project name is STIM+ (project code DF-STIM1), and the commercial name is Hydroxyal + Sterile injectable medical device for facial aesthetic treatment.

STIM+ (Hydroxyal+ - DF-STIM1) is a sterile injectable CaHA-based resorbable gel containing synthetic calcium hydroxyapatite (56% w/v) in a NaCMC/glycerin/PBS carrier, with lidocaine hydrochloride (3 mg/g - 0.3%) as an ancillary medicinal substance.

This investigation will include 75 participants to reach 60 evaluable and will be conducted as a single-arm, open-label, single-centre prospective study at CIDP Mauritius over a 52-week follow-up period, with the primary effectiveness assessment at 4 weeks and durability/safety follow-up at 26 and 52 weeks.

The dosage of STIM+ is individualized based on the participant's anatomical characteristics and the severity of the midface volume deficit, as assessed by the investigator. The device is administered by deep dermal or subdermal injection using a slow, retrograde technique in micro-aliquots. The volume injected per cheek should not exceed 2 ml per session, in accordance with the Instructions for Use. STIM+ is supplied with pre-filled syringes of 1.5 ml, and one or more syringes may be used to achieve the desired correction without exceeding the recommended limits.

Each box contains one graduated pre-filled 1.5 ml syringe of HYDROXAL+, a set of implant cards to ensure traceability, and an instruction leaflet.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
STIM+

Primary outcome(s)
1. Improvement in facial appearance and loss of volume in the cheeks measured using the Global Aesthetic Improvement Scale (GAIS), assessed by the investigator, at baseline (day -3 to day 0, pre-treatment), week 4 (day 28), week 26 (day 182), and week 52 (day 364) after injection

Key secondary outcome(s)

Completion date
17/03/2028

Eligibility

Key inclusion criteria
1. Male and female participants aged 30 to 70 years old
2. Any phototype
3. Any ethnicity (30% Caucasian panel)
4. Presenting Grade 2-4 on the Allergan Cheek Volume Scale
5. Seeking aesthetic treatment for midface (cheek) volume deficit
6. Willing to abstain from other facial aesthetic procedures in the mid-face during the study
7. Participants who have given their consent for photographs for illustration purposes
8. Participants in good general and mental health as determined by the investigator
9. Participants who can read and fully understand the aims of the study and its conduct and have given their free, informed and expressed written consent
10. Participants agree to cooperate, in full awareness of the study objectives, the necessity and the duration of the follow-up controls at the trial site to ensure perfect adherence to CIP
11. Participants who, in the judgement of the investigator, are likely to be compliant during the

study
12. Participants are willing and capable of following the study rules and a fixed schedule
13. Participants are willing and capable of signing an informed consent document (including the language)

Healthy volunteers allowed
Yes

Age group
Mixed

Lower age limit
30 Years

Upper age limit
70 Years

Sex
All

Total final enrolment
62

Key exclusion criteria
1. Participants with any systemic disorder or skin disease that would in any way confound interpretation of the study results
2. Participants with medical/surgical/severe allergy/anaphylactic shock history that, in the opinion of the Investigator, could compromise the safety of the participant or affect the outcome of the study
3. Participants have known risk of hypersensitivity to one of the components of the composition
4. Participants suffering from autoimmune disease
5. Participants having cutaneous disorders, inflammation or infection (herpes, acne, etc) at the treatment site or nearby
6. Participants for whom medical history shows a sensitivity that could lead to a reaction to the treatment
7. Participants with bleeding disorders or in participants who are undergoing treatment with thrombolytics or anticoagulants
8. Participants with a tendency to form keloids, hypertrophic scars or any other healing disorders
9. Participants who are currently following skin treatment
10. Pregnant or breastfeeding women or those considering a pregnancy during the study
11. Female participants of childbearing potential with a positive urine pregnancy test (UPT) at D-3-D0 visit
12. Participants who have been deprived of their freedom by administrative or legal decision or who are under guardianship
13. Participants who cannot be contacted by telephone in case of emergency
14. Participants 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. Prior adverse reaction to hyaluronic acid treatment (injectable or over-the-counter topical)
17. Connective tissue disorder
18. Active infection in treatment area

19. Active severe inflammatory disease in treatment areas such as atopic dermatitis and psoriasis
20. Treatment with toxin or filler in lower face below the orbital rim within the past 6 months

Date of first enrolment
25/11/2026

Date of final enrolment
19/03/2027

Locations

Countries of recruitment
Mauritius

Sponsor information

Organisation
Centre International de Développement Pharmaceutique (CIDP) Ltée

Funder(s)

Funder type

Funder Name
Louna Aesthetics

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available