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A study to test the safety and effectiveness of KYLIPS cheek filler for restoring volume in the midface area

Submission date
15/05/2025

Recruitment status
Recruiting

Registration date
23/05/2025

Overall study status
Ongoing

Last Edited
28/10/2025

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
KYLIPS medical device is classified as medical device and intended purpose of KYLIPS device is to improve facial skin quality attributes such as volume restoration, skin elasticity or firmness and skin texture. KYLIPS is intended to be used by healthcare professionals in accordance to local regulations for this kind of treatment. the purpose of this investigational clinical study is to confirm the clinical effectiveness and safety of the KYLIPS device in the intended use. The follow-up visits will be performed after 1 month, 6 months and 12 months.

Who can participate?
KYLIPS devices are intended to be administered to be used in healthy subjects aged between 30 and 60 years and who are seeking for aesthetic treatment of facial aging with the improvement of facial skin quality such as volume restoration, skin elasticity or firmness and skin texture.

What does the study involve?
The study duration is 12 months. Subjects will undergo a screening visit followed by a visit at D-3-D0 whereby several parameters will be measured for volume restoration, skin firmness/elasticity and texture (roughness).
At Baseline visit (D0), “KYLIPS” will be injected on both cheeks and a subjective evaluation will be done by the injector. After 4 weeks (W4), 26 weeks (W26), and 52 weeks (W52) skin parameters measured for volume restoration, skin firmness/elasticity and texture.

What are the possible benefits and risks of participating?
Injection of hyaluronic acid is generally well-tolerated, and most side effects are mild in intensity and transient in nature. They are related to the injection procedure rather than the implant itself. The most frequent adverse events associated with dermal fillers injections include bruising, redness, swelling, pain, tenderness, itching, rash, erythema (FDA, 2015; NHS, 2016).

Less common side effects are raised bumps or lumps in or under the skin (nodules or granulomas) that may need to be surgically removed, infection, open or draining wounds, a sore at the injection site, allergic reaction, necrosis (tissue death) (FDA, 2015).

The following rare side effects have also been reported (FDA, 2015 / FDA, 2021): severe allergic reaction (anaphylactic shock) that requires immediate emergency medical assistance, migration /movement of filler material from the site of injection, leakage or rupture of the filler material at the injection site (not relevant in the case of a HA and PN filler) or through the skin (which may result from tissue reaction or infection), the formation of permanent hard nodules, vision abnormalities, including blindness, stroke (due to cerebral ischemia or cerebral hemorrhage), injury to the blood supply, damage to the skin or the lips.

The observed complications with dermal fillers can be classified by onset of adverse events:
Early reactions (up to 24h after procedure to 4 weeks, according to Urdiales- Galvez et al. (2018))
• Vascular adverse event/soft-tissue necrosis
• Inflammatory reactions (acute/chronic)
• Infection
• Allergic reactions/hypersensitivity
• Injection-related events
• Pain
• Ecchymosis
• Erythema
• Bruising
• Bleeding
• Inappropriate/superficial placement
• Distant spread

Late reactions (more than 4 weeks, according to Urdiales-Galvez et al. (2018))
• Inflammatory reactions (acute/chronic)
• Infection
• Granuloma (typically chronic)
• Differential diagnosis
• Nodules
• Dyspigmentation
• Displacement of hyaluronic acid filler material

Where is the study run from?
KYLYS AESTHETICS SA (Switzerland)

When is the study starting and how long is it expected to run for?
May 2025 to February 2027

Who is funding the study?
KYLYS AESTHETICS SA (Switzerland)

Who is the main contact?
Dr Ounisha Mungur, o.mungur@cidp-cro.com
Bhavna SEWNUNDUN, b.sewnundun@cidp-cro.com

Contact information

Type(s)
Public

Contact name

Miss Bhavna Sewnundun

Contact details
BioPark Mauritius, SOCOTA Phoenicia
Sayed Hossen Road
Phoenix
Mauritius
73408
+230 4012600
b.sewnundun@cidp-cro.com

Type(s)
Scientific, Principal investigator

Contact name
Mrs PETKAR Gitanjali

Contact details
BioPark Mauritius, SOCOTA Phoenicia
Sayed Hossen Road
Phoenix
Mauritius
73408
+230 4012600
g.petkar@cidp-cro.com

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
A class III medical device study to evaluate the safety and effectiveness of KYLIPS injectable cheek filler in adults with midface volume deficit

Study objectives
The null hypothesis states that less than 40% of subjects are responders with GAIS. It is assumed that under the alternative hypothesis 65% of subjects are responders.
Using a two-sided exact one-sample binomial test, 55 subjects are required to show with a power of 90% a significant result (alpha = 5%).

Ethics approval required

Ethics approval required

Ethics approval(s)
approved 11/06/2025, Clinical Research Regulatory Council (Atchia Building, Suffren Street, Port-Louis, 11405, Mauritius; +230 (0)59439503; crrc@govmu.org), ref: 2324CMCL027

Study design
Prospective open interventional non-randomized study

Primary study design
Interventional

Study type(s)
Efficacy

Health condition(s) or problem(s) studied
Face skin quality improvement

Interventions
This study will be conducted as a prospective and open study to evaluate the effectiveness of the Medical Device on the improvement of skin quality by objective measurements of facial skin quality at 4 weeks (W4), 26 weeks (W26) and 52 weeks (W52) post injection.

Subjects will undergo a screening visit followed by a visit at D-3-D0 whereby several parameters will be measured for volume restoration, skin firmness/elasticity and texture (roughness).

At Baseline visit (D0), “KYLIPS” will be injected on both cheeks and a subjective evaluation will be done by the injector. After 4 weeks (W4), 26 weeks (W26), and 52 weeks (W52) skin parameters measured for volume restoration, skin firmness/elasticity and texture.

KYLIPS medical device is classified as a class III (rule 8, Chapter III of the Regulation (EU) 2017 /745 and rule 18) and class D - rule 8 as per the Guidance of Medical Devices Classification – MDS-G42 – Saudi FDA – v1.0/27-11-2019. KYLIPS device is a sterile, and resorbing gel of hyaluronic acid of bio fermentative origin.

KYLIPS device is a sterile, transparent and resorbing gel of hyaluronic acid of biofermentative origin. KYLIPS devices act by providing aesthetic benefits to patients who are seeking aesthetic treatment of deep skin depressions and lips enhancement at the level of the face. This medical device contains hyaluronic acid cross-linked with poly(N-isopropylacrylamide) that creates a volume in the skin tissues that corrects facial anatomy and treats the facial aging.

Each device has the following characteristics:
• Injectable resorbable gel (non-permanent gel),
• Based on hyaluronic acid substituted with poly (N isopropylacrylamide)
• Sterile and single use,
• Packaged in 1 mL plastic syringes with integrated luer-lock, in a volume of 1 mL,
• Accompanied by a single use sterile needle CE-marked compatible with luer-lock system,
• Equipped with a suitable backstop and plunger rod on the syringe,
• Presented in a secondary packaging that protects the integrity of each syringe,
• Stored either in ambient or refrigerated conditions for up to 36 months.

KYLIPS devices have the following properties:
Composition: Bioconjugate hyaluronic acid : 14 mg/mL
Phosphate buffer saline: q.s. 1 mL
Form: Injectable sterile gels in syringe
Mode of administration: KYLIPS is intended to be administrated via deep dermis injection or subdermally by an authorized health
professional
Primary Packaging: Syringe of 1 mL
Needle: 30G ½ (inch)
Secondary Packaging: Presented in a secondary packaging that protects the integrity of each syringe and equipped with a suitable backstop and plunger rod on the syringe
Storage: Between 2 and 25°C away from sunlight Up to 3 years of
expiry date

The raw materials and components which compose KYLIPS products are compliant with the European Pharmacopoeia when monographs exist and/or applicable normative standards.

The production of KYLIPS is subcontracted to a contract manufacturer which is specialised in the manufacturing of medical devices and pharmaceutical products.

Each box (= secondary packaging) of KYLIPS device contains two pre-filled syringes of KYLIPS, 4 needles and set of implant cards.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
KYLIPS

Primary outcome(s)
Effectiveness of injectable cheek filler “KYLIPS” 4 weeks (W4) after the injection using clinical evaluation of the global aesthetic improvement (GAIS) rated by the investigator.

Key secondary outcome(s))
1. Evaluate the improvement of mid-face volume deficit by clinical scoring at D-3 and D0, D0, 4 weeks (W4), 26 weeks (W26) and 52 weeks (W52) after injection by investigator using Allergan Cheek volume scale.
2. Evaluate the effectiveness of “KYLIPS” on the improvement of skin quality by objective measurements of skin texture (roughness) at 4 weeks (W4), 26 weeks (W26) and 52 weeks (W52) post injection with Antera 3D.
3. Evaluate the effectiveness of “KYLIPS” on the improvement of skin quality by objective measurements of skin firmness/elasticity by Cutometer® on 4 weeks (W4), 26 weeks (W26) and 52 weeks (W52) after injection.
4. The effectiveness of “KYLIPS” 4 weeks (W4) after the injection using clinical evaluation of the GAIS rated by the subject.
5. The effectiveness of “KYLIPS” 4 weeks (W4), 26 weeks (W26) and 52 weeks (W52) after the injection using clinical evaluation of the GAIS rated by the subject.
6. To evaluate the satisfaction of the injector on the injection quality using subjective evaluation

questionnaire.
7. To illustrate the treatment effect of the product through 2D photography and ¾ angle.
8. To assess the safety of the “KYLIPS” through the incidence of signs and symptoms of skin irritation or sensitivity (using Injection Site Reaction questionnaire from both subject and investigator) during the entire period of the study.
9. Patient satisfaction on the treatment outcomes using a subjective evaluation questionnaire completed at 4 weeks (W4), 26 weeks (W26) and 52 weeks (W52) post injection.
10. Additionally, standardized photography will be made for the purpose of efficacy illustration, subsequently image-analysed and scored by independent assessors for various features including Mid face volume deficit.

Completion date
08/02/2027

Eligibility

Key inclusion criteria
1. Female subjects
2. Aged between 30 to 60 years old
3. Subjects of any phototype
4. 50% Caucasian panel
5. Subject seeking increase in midface volume
6. Subjects seeking improvement of their skin quality
7. Subjects who have given their consent for photographs for illustration purposes
8. Subjects willing to abstain from other facial aesthetic procedures in the mid-face through the entire study duration
9. Subjects in good general and mental health in the opinion of the investigator
10. Subjects who have the ability to read and fully understand the aims of the study and its conduct and have given their free, informed and expressed written consent
11. Subjects agreeing 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 protocol
12. Subjects who, in the judgement of the investigator, are likely to be compliant during the study
13. Subjects willing and capable of following the study rules and a fixed schedule
14. Subjects willing and capable to sign an informed consent document (including the language)

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
30 years

Upper age limit
60 years

Sex
Female

Key exclusion criteria
1. Subject with any systemic disorder or skin disease that would in any way confound interpretation of the study results
2. Subjects with medical/surgical/severe allergy/anaphylactic shock history that, in the opinion of the Investigator, could compromise the safety of the subject or affect the outcome of the study
3. Subjects having known risk of hypersensitivity to one of the components of the composition
4. Subjects suffering from autoimmune disease
5. Subjects having cutaneous disorders, inflammation or infection (herpes, acne, etc.) at the treatment site or nearby
6. Subjects for whom medical history shows a sensitivity that could lead to a reaction to the treatment
7. Subjects with bleeding disorders or in subjects who are undergoing treatment with thrombolytics or anticoagulants
8. Subjects with a tendency to form keloids, hypertrophic scars or any other healing disorders
9. Subjects who are currently following a skin treatment
10. Pregnant or breastfeeding women or those considering a pregnancy during the study
11. Female subjects of childbearing potential with a positive urine pregnancy test (UPT) at D-3–D0
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. 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 area such as atopic dermatitis, psoriasis
20. Treatment with toxin or filler in lower face below the orbital rim within the past 6 months

Date of first enrolment
17/11/2025

Date of final enrolment
02/08/2026

Locations

Countries of recruitment
Mauritius

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

Phoenix
Mauritius
73408

Sponsor information

Organisation
KYLYS AESTHETICS SA

Funder(s)

Funder type
Industry

Funder Name
KYLYS AESTHETICS SA

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes