ISRCTN18337561 https://doi.org/10.1186/ISRCTN18337561

Safety and effectiveness clinical evaluation of the range of injectable HAR medical devices in facial aesthetic treatment

Submission date
22/10/2025

Recruitment status
No longer recruiting

Registration date
24/10/2025

Overall study status
Ongoing

Last Edited
24/10/2025

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
This clinical study is designed to confirm the safety and effectiveness of a specific group of injectable hyaluronic acid (HA) gels called HAR fillers. These products, which include Louna Filler Instant Refine, Shape & Volume, Glossy Lips, and Maxi Lift, are used for common aesthetic facial treatments. The primary objective is to prove that these HAR fillers offer a natural-looking, safe, and long-lasting correction for various signs of facial aging, such as wrinkles or volume loss.

Who can participate?
Adult volunteers between the ages of 18 and 65. Participants must have visible signs of facial aging that can be corrected by the fillers, such as noticeable wrinkles, areas where volume has been lost, or lips that they feel are too thin.

What does the study involve?
If you join the study, you will receive one aesthetic treatment using the appropriate HAR filler tailored to your specific needs. This injection will be performed by a medical professional who is trained in these specific procedures, following standard clinic conditions. After the initial treatment, we will monitor you for a total of 12 months with three follow-up evaluation visits at 1 month, 6 months, and 12 months. These check-ups are essential for us to assess the visible aesthetic improvement, how long the product lasts, and how well your body tolerates the filler over time.

What are the possible benefits and risks of participating?
The potential benefit is receiving the HAR filler treatment and the resulting aesthetic improvement at no cost or reduced cost, depending on the study site. As for risks, the most common side effects are minor and temporary, such as mild redness, slight swelling, or bruising at the spot where the injection was given. These effects typically clear up on their own within a few days. We are committed to participant safety and follow very strict international ethical and quality guidelines (Good Clinical Practice and ISO 14155) to ensure your safety, voluntary participation, and confidentiality throughout the entire study.

Where is the study run from?
Louna Aesthetics (France)

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

Who is funding the study?
Louna Aesthetics (France)

Who is the main contact?
Dr Siham Rharbaoui, siham.rharbaoui@cpt.eurofinseu.com

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Dr Siham Rharbaoui

Contact details
114 Boulevard du 11 Novembre 1918
Villeurbanne
France
69100
+33(0)4 72 89 36 56
siham.rharbaoui@cpt.eurofinseu.com

Additional identifiers

Clinical Trials Information System (CTIS)
2025-A02340-49

Protocol serial number
25-1761

Study information

Scientific Title
Safety and effectiveness clinical evaluation of the range of injectable HAR medical devices in facial aesthetic treatment

Study objectives
The HAR device will aesthetically modify facial anatomy and treat facial aging with the correction of facial wrinkles or folds, the definition or enhancement of the lips, and the restoration or enhancement of the facial volume.

Ethics approval required
Ethics approval required

Ethics approval(s)
notYetSubmitted 23/10/2025, North-West I Committee for the Protection of Persons (Université de Rouen- Factulte de Médecine /Pharmacie Bâtiment Stewart 6ème Etage - Rue du Professeur Stewart, Rouen, 76000, France; +33 232888446; cpp.nordouest1@chu-rouen.fr), ref: Reference number not provided

Study design
Interventional open label study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Subjects presenting moderate to severe facial aging signs, including perioral lines, nasolabial folds, infraorbital hollows, cheek/chin volume loss, or thin lips, seeking aesthetic improvement through dermal filler injection.

Interventions
HAR device is sterile, transparent and resorbing gel of crosslinked (with BDDE) hyaluronic acid of non-animal origin.

The indication for use of the HAR devices is the aesthetic modification of the facial anatomy and the aesthetic treatment of the facial aging with the correction of facial wrinkles or folds, the definition or enhancement of the lips, and the restoration or enhancement of the facial volume.

Treatment with HAR is only intended to be administrated by an authorized healthcare professional in accordance with local regulation for this kind of treatment. HAR is classified as a class III (rule 7, Chapter III of the Regulation (EU) 2017/745) medical device.

A qualified healthcare practitioner will inject the device (the procedure takes roughly 20 minutes). The treatment aims to last between 6 to 12 months. In the frame of the study, only one injection will be carried out. No touch up or retreatment is planned in the course of the study.

Intervention Type
Device

Phase
Not Applicable

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

Primary outcome(s)
Improvement of the zone treated with the overall HAR range of devices as assessed by an independent investigator, one month (M1) after treatment, using the GAIS. An improvement is defined as a subject with “very much improved”, “much improved” or “improved” score on the GAIS.

Key secondary outcome(s))
1. Injection Site Reaction six month (M6) and twelve month (M12) after treatment as evaluated by an independent investigator
2. Injection Site Reaction one month (M1), six month (M6) and twelve month (M12) after treatment as evaluated by the subjects.
3. AEs throughout the study
4. Improvement of the zone treated with the overall HAR range of devices as assessed by an independent investigator, six (M6) and twelve (M12) months after treatment, using the GAIS.
5. Improvement of the zone treated with each HAR device for all indications independently as assessed by the independent investigator, one, six and twelve months after treatment, using the GAIS.
6. Improvement of the zone treated with the HAR range of devices overall as assessed by the subjects, one, six and twelve months after treatment, using the GAIS.
7. Improvement of the zone treated with each HAR device for all indications independently as assessed by the subjects, one, six, and twelve months after treatment, using the GAIS
8. Effectiveness on wrinkles/lines filling of the device HAR 1 used in the peri-oral lines as assessed by the independent investigator one, six and twelve months after treatment, using the Bazin Upper lip wrinkles scale.
9. Effectiveness on folds filling of the device HAR 2 used in the nasolabial folds as assessed by the independent investigator one, six and twelve months after treatment, using the WSRS scale.
10. Effectiveness on volume restauration of the device HAR 2 used in the cheeks/cheekbones as assessed by the independent investigator, one, six and twelve months after treatment, using the Ascher lipoatrophy scale.
11. Effectiveness on lip volume increase of the device HAR 2 used in lips as assessed by the independent investigator one, six and twelve months after treatment, using the Rossi scale.
12. Effectiveness on volume restauration of the device HAR 3 used in the cheeks/cheekbones as assessed by the independent investigator, one, six and twelve months after treatment, using the Ascher lipoatrophy scale.
13. Injector’s satisfaction on the injection quality using a questionnaire completed immediately after injection on D0.
14. Illustration of the treatment effect one, six and twelve months after treatment compared to baseline by photographs taking.

Completion date
30/06/2027

Eligibility

Key inclusion criteria
1.Healthy Subject.
2.Sex: male or female.
3.Age: between 18 and 70 years.
4.Subject seeking an improvement of her/his face aspect with HA filler.
5.*For group 1: Subject with moderate to severe peri-oral lines (score 3 to 5 on Bazin Upper lip scale) and/or subject seeking improvement of infraorbital hollow enhancement.
*For group 2: Subject with moderate to severe nasolabial folds (score 3 to 4 on WSRS scale) and /or subjects with mild to moderate cheeks/cheekbones volume deficit (score 3 to 4 on Ascher lipoatrophy scale);
*For group 3: Subject with thin lips (score 1 or 2 for superior and/or inferior lip on the Rossi scale) and seeking an improvement of lip volume

*For group 4: Subject with moderate to severe cheeks/cheekbones volume deficit (score 3 to 4 on Ascher lipoatrophy scale) and/or subject seeking improvement of chin enhancement.
6.Subject with a stable weight since the last 6 months and who agree to keep a stable weight during the study.
7.Subject having given freely and expressly his/her informed consent.
8.Subject psychologically able to understand the study related information and to give a written informed consent.
9.Subject affiliated to a health social security system.
10.Female of childbearing potential should use a contraceptive regimen recognized as effective since at least 12 weeks and during all the study.

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
70 years

Sex
All

Key exclusion criteria
In terms of population:
1. Pregnant or nursing woman or planning a pregnancy during the study.
2. Subject who had been deprived of their freedom by administrative or legal decision or who is under guardianship.
3. Subject in a social or sanitary establishment.
4. Subject suspected to be non-compliant according to the investigator's judgment.
5. Subject having received a total of 6.000 euros as compensations for her/his participation in clinical research in the last 12 months, including their participation in the present study.
6. Subject enrolled in another study or whose non-enrollment period is not over.
7. Subject with scar(s), mole(s), hair or any other lesion on the studied zones which might interfere with the evaluation (tattoo, permanent make-up…).

In terms of associated pathology:
8. Subject suffering from a severe or progressive disease or any other pathology that may interfere with the evaluation of the study results and/or subject safety.
9. Subject with known history of or suffering from autoimmune disease and/or immune deficiency.
10. Subject suffering from active disease such as inflammation, infection, tumours, inflammatory and/or infectious cutaneous disorders (herpes, severe acne, severe rosacea, porphyria …) in the 6 months before screening visit.
11. Subject with a history of streptococcal disease or an active streptococcus infection.

12. Subject prone to develop inflammatory skin conditions or having tendency to bleeding disorders.
13. Subject predisposed to keloids or hypertrophic scarring or having healing disorders.
14. Subject having history of severe allergy or anaphylactic shock including known hypersensitivity to one of the components of the investigational device (i.e Hyaluronic acid), to antiseptic solution (Diaseptyl®), to lidocaine or to amide-type anaesthetics
15. Subject with symptoms consistent with COVID-19 or are suffering from ongoing symptoms from previous COVID-19 infection[CC1.1]

Relating to previous or ongoing treatment:
16. Any medication which may interfere, at the interpretation of the investigator, with the study objectives.
17. Subject having received treatment with a laser, a dermabrasion, a surgery, a chemical peeling or any other procedure based on active dermal response on the face within the past 6 months or who plans to undergo any of these procedures during the study.
18. Subject having received within the past 18 months or planning to receive during the study any injections outside of those in the study protocol including non-permanent and semi-permanent fillers (e.g., HA, Calcium Hydroxyapatite) or botulinum neurotoxin [CC2.1]on or near the treated zone.
19. Subject having received within the past 9 months or planning to receive during the study mesotherapy injections on or near the treated zone.[CC3.1]
20. Subject having received at any time or planning to receive a permanent filler on the face (e. g., polylactic acid, Polymethylmethacrylate, silicone) during the study.
21. Subject with subcutaneous retaining structure on the face (meshing, threads, gold strand).
22. Subject using medication such as aspirin, nonsteroidal anti-inflammatory drugs (NSAIDs), antiplatelet agents, thrombolytics or anticoagulants within one week prior to injection visit or being a chronic user.
23. Subject undergoing a topical treatment on the test area or a systemic treatment:
23.1. anti-inflammatory medication and/or antihistamines within the past 2 weeks and during the study,
23.2. corticosteroids within the past 2 weeks and during the study,
23.3. retinoids and/or immunosuppressors within the past 3 months and during the study.
In terms of lifestyle
24. Intensive exposure to sunlight or UV-rays within the previous month and/or planning to do so during the study.
25. Subject planning to change her/his life habits during the study

Date of first enrolment
01/12/2025

Date of final enrolment
24/02/2026

Locations

Countries of recruitment
France

Study participating centre

Eurofins Dermscan Pharmascan
114 Boulevard du 11 Novembre 1918
Villeurbanne
France
69100

Sponsor information

Organisation
Louna Aesthetics

Funder(s)

Funder type
Industry

Funder Name
Louna Aesthetics

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