

# Safety and effectiveness clinical evaluation of the range of injectable medical devices HYDRAGEL C in facial aesthetic treatment

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<b>Registration date</b> 21/08/2023	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 21/08/2023	<b>Condition category</b> Skin and Connective Tissue Diseases	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English Summary

### Background and study aims

Facial aging is a natural process that occurs over time, but many seek cosmetic procedures to restore a more youthful appearance. Hydragel C is a new line of injectable gels being studied to treat common signs of facial aging like wrinkles, lost volume, and thin lips.

The aim is to confirm the safety and effectiveness of Hydragel C for aesthetic facial rejuvenation. Hydragel C is made of resorbable biopolymers among with hyaluronic acid, a substance also found naturally in the skin. When injected into facial tissue, hyaluronic acid provides volume to fill in wrinkles and creases. A second component called polynucleotide is added to reinforce the gel filler and prolong its effects.

The aim is to confirm that Hydragel C safely and effectively treats wrinkles, lost facial volume, and thin lips.

### Who can participate?

Adults between 18-70 years old of any gender can participate. Participants must want treatment to improve the appearance of wrinkles, lost facial volume, or thin lips that bothers them. They must be in overall good health with no history of severe allergic reactions or certain skin conditions like eczema or psoriasis near the treatment area. Pregnant and breastfeeding women cannot participate due to a lack of data on risks.

### What does the study involve?

Eligible participants will be treated with Hydragel C injections into their wrinkles, folds, cheeks, or lips as needed. There are three customized Hydragel C gels for different injection depths and facial areas. An experienced dermatologist or plastic surgeon will administer the injections using careful techniques to maximize safety and achieve natural-looking results.

After treatment, follow-up visits are scheduled at 1 month, 6 months, and 12 months. The doctor will examine and photograph the face. Any improvement in wrinkles, facial volume, and lip fullness from Hydragel C will be evaluated using standardized scales. Participants will also assess their own satisfaction with the results. These measures will reveal how long the cosmetic benefits of Hydragel C last.

What are the possible benefits and risks of participating?

Participants may gain aesthetic improvement in wrinkles, restored facial contours, and fuller lips. These can help participants look more refreshed and youthful. Potential risks are similar to other cosmetic fillers. Mild swelling, bruising, redness, and tenderness often occur after injections but usually resolve within a week. Less common side effects include small lumps under the skin and unevenness. Serious complications like infection and blocked blood supply are rare. Participants will be fully informed of all potential side effects before agreeing to enroll.

Where is the study run from?

Eurofins DermScan Pharmascan (France)

When is the study starting and how long is it expected to run for?

June 2023 to June 2025

Who is funding the study?

Louna Aesthetics (France)

Who is the main contact?

Dr F. Hadjab, f.hadjab@lounaaesthetics.com.

## Contact information

### Type(s)

Principal Investigator

### Contact name

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## Additional identifiers

### EudraCT/CTIS number

Nil known

### IRAS number

### ClinicalTrials.gov number

Nil known

### Secondary identifying numbers

23E0242

## Study information

**Scientific Title**

Assessment of the safety and effectiveness of the use of HYDRAGEL C in the treatment of the periorbital and nasolabial fold wrinkles, cheeks and cheekbones

**Study hypothesis**

HYDRAGEL C induces a global aesthetic improvement of the periorbital and perioral wrinkles and cheekbones/cheeks

**Ethics approval required**

Ethics approval required

**Ethics approval(s)**

Not yet submitted (France)

**Study design**

Open intra-individual single-dose single-center trial

**Primary study design**

Interventional

**Secondary study design**

Non randomised study

**Study setting(s)**

Other

**Study type(s)**

Other

**Participant information sheet****Condition**

Subjects across groups present with moderate to severe facial aesthetic concerns, including perioral lines, nasolabial folds, lip volume deficits, and cheeks/cheekbones volume deficit, as gauged by various dermatological scales

**Interventions**

75 will be treated in total with Hydragel C divided into groups :

Group 1: At least 25 subjects treated in peri-oral lines and lips contour

Group 2: At least 25 subjects treated in nasolabial folds and/or in lips

Group 3: At least 25 subjects treated in cheek/cheekbones

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

**Pharmaceutical study type(s)**

Not Applicable

**Phase**

Not Applicable

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

Hydragel C / Xylocaine / EMLA cream

**Primary outcome measure**

Aesthetic improvement measured using the Global Aesthetic Improvement Scale (GAIS) evaluated by an independent live assessor 1 month after treatment (M1)

**Secondary outcome measures**

1. The safety of the HYDRAGEL C range and of each HYDRAGEL C device independently will be assessed by:
  - 1.1. Collection of immediate and early Injection Site Reactions (ISRs) by the subjects on a daily log every day up to 1 month after treatment
  - 1.2. Collection of immediate and early ISRs by the independent investigator immediately and one (M1), six (M6) and twelve months (M12) after treatment
  - 1.3. Collection of AEs throughout the study
2. Proportion of subjects having an improvement of the zone treated with the overall HYDRAGEL C range of devices as assessed using the GAIS by an independent investigator, six (M6) and twelve (12M) months after treatment
3. Proportion of subjects having an improvement of the zone treated with each HYDRAGEL C device for the four indications independently as assessed using the GAIS by an independent investigator, one (M1), six (M6) and twelve (12M) months after treatment
4. Proportion of subjects having an improvement of the zone treated with the HYDRAGEL C range of devices overall as assessed using the GAIS by the subjects, one (M1), six (M6) and twelve (12M) months after treatment
5. Proportion of subjects having an improvement of the zone treated with each HYDRAGEL C device for the four indications independently as assessed using the GAIS by the subjects, one (M1), six (M6) and twelve (12M) months after treatment
6. Evaluation of the effectiveness on wrinkles/lines filling of the device HYDRAGEL C1 used in the peri-oral lines as assessed using the Bazin Upper lip wrinkles scale by an independent investigator one (M1), six (M6) and twelve (12M) months after treatment
7. Evaluation of the effectiveness on lips volume increase of the device HYDRAGEL C2 used in lips as assessed using the Rossi scale by an independent investigator one (M1), six (M6) and twelve (12M) months after treatment
8. Evaluation of the effectiveness on folds filling of the device HYDRAGEL C2 used in the nasolabial folds as assessed using the WSRS scale by an independent investigator one (M1), six (M6) and twelve (12M) months after treatment
9. Evaluation of the effectiveness on volume restauration of the device HYDRAGEL C3 used in the cheeks/cheekbones as assessed using the Ascher lipoatrophy scale by an independent investigator at one (M1), six (M6) and twelve (12M) months after treatment
10. Injector's satisfaction with the injection quality assessed using a questionnaire completed immediately after injection on D0
11. Illustration of the treatment effect by taking photographs at baseline, one (M1), six (M6) and twelve (12M) months after treatment

**Overall study start date**

23/06/2023

**Overall study end date**

30/06/2025

## **Eligibility**

**Participant 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
  - \*For group 1: Subject with moderate to severe peri-oral lines (score 3 to 5 on Bazin Upper lip scale) and lips contour requiring redefinition
  - \*For group 2: Subject with moderate to severe nasolabial folds (score 3 to 4 on the WSRS scale) and/or seeking an improvement of lip volume (score 1 or 2 for superior and/or inferior lip on the Rossi scale)
  - \*For group 3: Subject with moderate to severe cheeks/cheekbones volume deficit (score 3 to 4 on Ascher lipoatrophy scale)
5. Subject with a stable weight for the last 6 months and who agrees to keep a stable weight during the study
6. Subject having given her/his free, express, and informed consent
7. Subject psychologically able to understand the information related to the study, and to give their written informed consent
8. Subject registered with a social security scheme
9. Women of childbearing potential should use a contraceptive method considered effective for at least 12 weeks and throughout the study

**Participant type(s)**

Healthy volunteer

**Age group**

Adult

**Lower age limit**

18 Years

**Upper age limit**

70 Years

**Sex**

Both

**Target number of participants**

75

**Participant exclusion criteria**

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 6000 euros as compensation 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)

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 a history of severe allergy or anaphylactic shock including known hypersensitivity to one of the ingredients of the investigational device (i.e. HA), seafood, to antiseptic solution (Diasseptyl®) or to lidocaine amide-type anaesthetics (EMLA®), related to previous or current treatments

Previous or ongoing treatment:

15. Subject having received a dose of COVID-19 vaccine within the 14 days prior to injection or planning to receive a dose in the 3 weeks following injection

16. Any medication which may interfere, at the interpretation of the investigator, with the study objectives

17. Subject having received treatment with a laser, ultrasound or radiofrequency treatment, a dermabrasion, 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 fillers (e.g., HA, Calcium Hydroxyapatite) or autologous fat on or near the treated zone

19. Subject having received within the past 9 months or planning to receive during the study any injections outside of those in the study protocol including mesotherapy or botulinum neurotoxin on or near the treated zone

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

#### **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

26. Subject with an excessive consumption of alcohol (more than 2 glasses of wine per day) and /or tobacco (more than 10 cigarettes per day)

#### **Recruitment start date**

01/01/2024

#### **Recruitment end date**

01/04/2024

## **Locations**

#### **Countries of recruitment**

France

#### **Study participating centre**

**Eurofins Dermscan Pharmascan**

114 Boulevard du 11 Novembre 1918

Villeurbanne

France

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## **Sponsor information**

#### **Organisation**

Louna Aesthetics

#### **Sponsor details**

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#### **Sponsor type**

Industry

## **Funder(s)**

**Funder type**

Industry

**Funder Name**

Louna Aesthetics

## Results and Publications

**Publication and dissemination plan**

Planned publication in a high-impact peer-reviewed journal

**Intention to publish date**

30/12/2025

**Individual participant data (IPD) sharing plan**

The datasets generated during and/or analysed during the current study are not expected to be made available because this is not needed by the sponsor. The sponsor will only establish a global database with all participants data. Data will be kept by the site for 1 year after the end of the trial, then data will be archived for 15 years by a CRO's subcontractor

**IPD sharing plan summary**

Not expected to be made available