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

Submission date
10/08/2023

Recruitment status
No longer recruiting

Registration date
21/08/2023

Overall study status
Completed

Last Edited
21/08/2023

Condition category
Skin and Connective Tissue Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

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

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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 objectives
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

Health condition(s) or problem(s) studied
Subjects across groups present with moderate to severe facial aesthetic concerns, including peri-oral 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

Completion date
30/06/2025

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
*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

Key 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 (Diaseptyl®) 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)

Date of first enrolment
01/01/2024

Date of final enrolment
01/04/2024

Locations

Countries of recruitment
France

Study participating centre
Eurofins Dermscan Pharmascan
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Sponsor information

Organisation
Louna Aesthetics

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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