ISRCTN37981524 https://doi.org/10.1186/ISRCTN37981524

Evaluation of the injectable medical device Hydragel A2 for skin quality improvement

Submission date
12/10/2023

Recruitment status
No longer recruiting

Registration date
17/10/2023

Overall study status
Completed

Last Edited
09/07/2024

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
Hydragel A2 is classified as a medical device and its intended purpose is to improve skin quality attributes such as skin elasticity and skin hydration, and to correct mild skin depression. Hydragel A2 is intended to be used by healthcare professionals in accordance with local regulations for this kind of treatment. The aim of this study is to evaluate the safety and effectiveness of Hydragel A2 in the improvement of skin quality at 2 and 6 weeks post injection.

Who can participate?
Healthy adults aged between 30 to 60 years old seeking an improvement in the skin of the face

What does the study involve?
The study duration is 4 months. Participants will undergo a visit for screening followed by measurements of skin density, thickness, elasticity, hydration and brightness. The injection of Hydragel A2 will be performed on both cheeks and a subjective evaluation will be carried out by the injector.

What are the possible benefits and risks of participating?
Hydragel A2 fillers have been widely used for facial rejuvenation for the past 20 years. Most treated subjects reported that they would recommend Hydragel A2 dermal fillers to their peers for facial rejuvenation.
The anticipated clinical benefits are the aesthetic improvement of facial skin quality and skin radiance in treated subjects. Skin quality improvement is defined as improvement of skin elasticity and firmness.
Injection with a Hydragel A2 device is less invasive and less permanent compared to surgical methods such as facial lifting or autologous fat transfer.
The following risks and expected adverse events are foreseen with Hydragel A2 devices:
Events which are naturally resolved within 1 week in most cases:
1. Injection-related events and/or inflammatory reactions such as bleeding, ecchymosis, erythema, haematoma, skin redness, bruising, swelling, oedema and infection which may be associated with local pain or itching, occurring after injection.

2. Sensitivity at the injection site.
3. Hardness, lump or nodule at the injection site.
4. Skin coloration or discoloration at the injection site.

Events which will have delayed resolution after the injection:
1. Immediate or delayed hypersensitivity to hyaluronic acid and/or to tranexamic acid.
2. Infection or reactivation of a previous infection.
3. Displacement of the gel.
Inflammatory reactions which persist for more than one week, or any other adverse event which develops, must be reported to the investigator. In this case, if required, the investigator can use an appropriate treatment.

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

When is the study starting and how long is it expected to run for?
June 2023 to August 2024

Who is funding the study?
Louna Aesthetics (France)

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

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Protocol serial number
2223CMPH145

Study information

Scientific Title

Safety and effectiveness clinical evaluation of injectable medical device hydragel A2 in the improvement of skin quality

Study objectives
The null hypothesis states that less than 40% of subjects are responders with global aesthetic improvement (GAIS). It is assumed that under the alternative hypothesis 65% of subjects are responders. Using a two-sided exact one-sample binomial test, 40 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 17/01/2024, Clinical Research Regulatory Council (Atchia Building, Suffren Street, Port-Louis, 11405, Mauritius; +230 (0)59439503; crrc@govmu.org), ref: 2223CMPH145

Primary study design
Interventional

Study design
Prospective open study

Study type(s)
Efficacy

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

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 skin quality at 2 weeks and 6 weeks post-injection.

Participants will undergo a visit at D-30 for screening followed by a visit at D-3-D0 whereby several parameters will be measured for skin density, thickness, elasticity, and hydration.

At the baseline visit (D0), HYDRAGEL A2 will be injected on both cheeks and a subjective evaluation will be done by the injector. After 2 weeks (visit W2) and 6 weeks (visit W6), skin parameters will be measured for density, thickness, elasticity, and hydration.

Device classification
HYDRAGEL A2 is classified as a class III (rule 7, Chapter III of the Regulation (EU) 2017/745 and rule 18) medical device.

Description of the investigational device
HYDRAGEL A2 device is a sterile, translucent and resorbing gel of hyaluronic acid of biofermentative origin. Polynucleotide in the form of PDRN a substance widely used in the cosmetic industry, is incorporated to the gel to protect the HA molecules against free radicals. The content of HYDRAGEL A2 vial is sterilised by moist heat.

HYDRAGEL A2 has the following properties:
1. Injectable resorbable gel (non-permanent gel)
2. Sterile and single use
3. Packaged in a 6 ml glass vial, in a volume of 3.0 ml
4. Presented in a secondary packaging that protects the integrity of each vial
5. Stored either in ambient (2 to 25°C) conditions for 36 months

The raw materials and components which compose HYDRAGEL A2 products are compliant with the European Pharmacopoeia when monographs exist and/or applicable normative standards.

The production of HYDRAGEL A2 is subcontracted to a contract manufacturer which is specialised in the manufacturing of medical devices and pharmaceutical products.

Each box (secondary packaging) of HYDRAGEL A2 device contains three pre-filled vials of HYDRAGEL A2 and a set of implant cards.
The composition is below:
HYDRAGEL A2
1. Hyaluronic acid: 5 mg/ml
2. Polynucleotide: 7.5 mg/ml
3. Phosphate buffer and niacinamide q.s. 1 ml

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Hydragel A2

Primary outcome(s)
The effectiveness of “HYDRAGEL A2” assessed using clinical evaluation of the global aesthetic improvement (GAIS) rated by the investigator at 2 weeks (W2) after the injection

Key secondary outcome(s)
1. Skin quality assessed by objective measurements of skin texture (roughness) at 2 and 6 weeks post-injection with Antera 3D
2. Skin quality assessed by objective measurements of:
2.1. Skin firmness/elasticity by Cutometer®
2.2. Skin hydration by Corneometer®
2.3. Skin density and thickness using Dermascan
at 2 and 6 weeks after injection
3. Proportion of subjects having an improvement of the zone treated with the overall VISCOL range of devices as assessed by an independent investigator using the GAIS at 6 weeks (W6) after treatment
4. The satisfaction of the injector on the injection quality assessed using a subjective evaluation questionnaire at Day 0
5. The treatment effect of the product assessed using 2D photography at Week 2 and Week 6
6. The safety of the HYDRAGEL A2 through the incidence of signs and symptoms of skin irritation or sensitivity (using the Injection Site Reaction questionnaire) during the entire period of the study

7. The subject’s satisfaction with global aesthetic improvement (GAIS) at 2 weeks and 6 weeks after the injection
8. The effectiveness of HYDRAGEL A2 assessed using clinical evaluation of the GAIS rated by the investigator at 2 weeks and 6 weeks after the injection
9. Patient satisfaction with the treatment outcomes using a subjective evaluation questionnaire completed at 2 weeks (W2) and 6 weeks (W6) after treatment

Completion date
16/08/2024

Eligibility

Key inclusion criteria
Current inclusion criteria as of 12/02/2024:

1. Female or male
2. Any ethnicity
3. Skin phototype (according to Fitzpatrick scale) from II to V
4. Aged 30 to 60 years old
5. Seeking improvement of their skin quality
6. Have given consent for photographs for illustration purposes
7. Willing to abstain from other facial aesthetic procedures in the mid-face through the entire study duration
8. In good general and mental health in the opinion of the investigator
9. 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
10. 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
11. In the judgement of the investigator, are likely to be compliant during the study
12. Willing and capable of following the study rules and a fixed schedule
13. Willing and capable of signing an informed consent document (including the language)

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Previous inclusion criteria:

1. Female or male
2. Any ethnicity
3. Skin phototype (according to Fitzpatrick scale) from II to V
4. Aged 18 to 45 years old
5. Seeking improvement of their skin quality
6. Have given consent for photographs for illustration purposes
7. Willing to abstain from other facial aesthetic procedures in the mid-face through the entire study duration
8. In good general and mental health in the opinion of the investigator
9. 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
10. 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

11. In the judgement of the investigator, are likely to be compliant during the study
12. Willing and capable of following the study rules and a fixed schedule
13. Willing and capable of signing 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
All

Key exclusion criteria
1. Any systemic disorder or skin disease that would in any way confound the interpretation of the study results
2. 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. Known risk of hypersensitivity to one of the components of the IP composition
4. Suffering from autoimmune disease
5. Cutaneous disorders, inflammation or infection (herpes, acne, etc.) at the treatment site or nearby
6. Medical history shows a sensitivity that could lead to a reaction to the treatment
7. Bleeding disorders or undergoing treatment with thrombolytics or anticoagulants
8. A tendency to form keloids, hypertrophic scars or any other healing disorders
9. 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. Deprived of their freedom by administrative or legal decision or who is under guardianship
13. Cannot be contacted by telephone in case of emergency
14. 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

Date of first enrolment
28/05/2024

Date of final enrolment
01/07/2024

Locations

Countries of recruitment
Mauritius

Study participating centre
CIDP
BioPark Mauritius, SOCOTA Phoenicia
Sayed Hossen Road
Phoenix
Mauritius
73408

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