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Safety and effectiveness clinical evaluation of injectable medical device Hydragel A1 in the skin quality improvement

Submission date	**Recruitment status**	[X] Prospectively registered
11/04/2023	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
02/05/2023	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
11/08/2023	Other	[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Hydragel A1 is classified as a medical device. Hydragel A1 device is a sterile, transparent and resorbing gel of hyaluronic acid (HA) of biofermentative origin. Tranexamic acid, a substance widely used in the cosmetic industry, is incorporated into the gel to improve the skin radiance. The intended purpose of Hydragel A1 devices is to improve facial skin quality such as skin elasticity or firmness and facial skin radiance. Hydragel A1 is intended to be used by healthcare professionals in accordance with local regulations for this kind of treatment.

Who can participate?
Healthy adults aged between 18 to 45 years old seeking an improvement in the skin of the face

What does the study involve?
This exploratory Clinical Study including 40 subjects aims to collect in prospective manner safety and performance clinical data. The study duration is 6 months. This study will be conducted as an experimental and open study to evaluate the effectiveness of the Medical Device on the improvement of skin quality by objective measurements of skin roughness/texture at 2 weeks post-second injection. Subjects will undergo a visit for screening at D-30 followed by a visit at D-3-D0 whereby several parameters will be measured for skin density, thickness, elasticity, hydration and brightness. At the Baseline visit (D0), the first injection of Hydragel A1 will be performed on both cheeks and a subjective evaluation will be done by the injector. After 2 weeks at visit W2, a second injection will be done followed by the subjective evaluation by the injector. At 2 weeks and 8 weeks after the second injection, i.e. visit W4 and visit W10, skin parameters will be measured for density, thickness, elasticity, hydration and brightening.

What are the possible benefits and risks of participating?
Anticipated benefits :
HA fillers have been widely used for facial rejuvenation for the past 20 years. A large majority of treated subjects reported that they would recommend HA 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 the improvement of skin elasticity and firmness. Injection with HA device improves the self-esteem and confidence of the subject.
Injection with HA device is less invasive and less permanent compared to surgical methods such as facial lifting or autologous fat transfer.

Anticipated risks:
The following risks and expected adverse events are foreseen with Hydragel A1 devices:
- Events which are naturally resolved within one week in most cases:
• Injection-related events and/or inflammatory reactions such as bleeding, ecchymosis, erythema, hematoma, skin redness, bruising, swelling, odema and infection which may be associated with local pain or itching, occurring after injection.
• Sensitivity at the injection site.
• Hardness, lump or nodule at the injection site.
• Skin coloration or discoloration at the injection site.
- Events which will have delayed resolution after the injection:
• Immediate or delayed hypersensitivity to hyaluronic acid and/or to tranexamic acid.
• Infection or reactivation of a previous infection.
• Displacement of the gel.

Where is the study run from?
Louna Aesthetics (France) is the sponsor. Study conduct will take place in Mauritius at CIDP.

When is the study starting and how long is it expected to run for?
February 2023 to January 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)
Scientific

Contact name
Dr Ounisha Mungur

Contact details
BioPark Mauritius
SOCOTA Phoenicia
Sayed Hossen Road
Phoenix
Mauritius
73408
+23058566989
o.mungur@cidp-cro.com

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
2223CMPH095

Study information

Scientific Title
Safety and effectiveness clinical evaluation of injectable medical device Hydragel A1 in the skin quality improvement

Study objectives
Hydragel A1 device will improve facial skin quality, such as skin elasticity, firmness and facial skin radiance.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 28/06/2023, Clinical Research Regulatory Council (2nd Floor, Bacha Building Right Wing, Cathedral Square, Port-Louis, -, Mauritius; +230 59439503; crrc@govmu.org), ref: None provided

Study design
Interventional open-label study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Patient seeking aesthetic treatment of the facial skin quality such as skin elasticity or firmness and facial skin radiance

Interventions
Hydragel A1 device is a sterile, transparent and resorbing gel of hyaluronic acid of biofermentative origin. Tranexamic acid, a substance widely used in the cosmetic industry, is incorporated into the gel to improve skin radiance. The intended purpose of the Hydragel A1 device is to improve facial skin quality such as skin elasticity or firmness and facial skin radiance. Hydragel A1 is intended to be used by healthcare professionals in accordance with local regulations for this kind of treatment. Hydragel A1 is classified as a class III (rule 7, Chapter III of the Regulation (EU) 2017/745) medical device.

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 roughness/texture at 2 weeks post 2nd injection.

Subjects 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, hydration and brightness.

At the Baseline visit(D0), the first injection of Hydragel A1 will be injected on both cheeks and a subjective evaluation will be done by the injector. After 2 weeks at visit W2, a second injection will be done followed by the subjective evaluation by the injector.

At 2 weeks and 8 weeks after the second injection, i.e. visit W4 and visit W10, skin parameters will be measured for density, thickness, elasticity, hydration and brightness.

This exploratory Clinical Study includes 40 subjects and aims to collect prospective safety and performance clinical data. The study duration is 6 months.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Hydragel A1 device

Primary outcome(s)
The proportion of subjects having an improvement of the zone treated measured using the Global Aesthetic Improvement Scale (GAIS) as assessed by the investigator, 4 weeks (W4) after the first injection.

An improvement is defined as a subject with a “very much improved”, “much improved” or “improved” score on the GAIS

Key secondary outcome(s))
1. The safety and tolerance of Hydragel A1 measured by assessing the incidence of signs and symptoms of skin irritation or sensitivity using an Injection Site Reaction questionnaire during the entire period of the study. For this purpose, AEs and SAEs will also be monitored.
2. The effectiveness of Hydragel A1 at improving skin quality by objective measurements of skin roughness/texture using the Antera 3D camera for skin analysis at 4 and 10 weeks after the first injection. The following effectiveness parameters of Hydragel A1 will be evaluated:
2.1. Skin firmness/elasticity by Cutometer®
2.2. Skin hydration by Corneometer®
2.3. Skin density & thickness through Dermascan
2.4. Skin brightness using Chromameter
3. The effectiveness of Hydragel A1 10 weeks after the 1st injection using clinical evaluation of the GAIS rated the investigator.
4. The subject’s satisfaction on global aesthetic improvement (GAIS) 2 weeks, 4 weeks and 10 weeks after the 1st injection.
5. The injection satisfaction on the injection quality using subjective evaluation questionnaire.

Additionally, standardized photography will be made for the purpose of efficacy illustration, subsequently image-analyzed and scored by independent assessors for various features including Mid-face volume deficit.

Completion date
25/01/2024

Eligibility

Key inclusion criteria
1. Female and male subjects
2.Fitzpatrick skin of the face from III to V
3. Aged between 18 to 45 years old
4. Subjects seeking an improvement in their skin brightness
5. Subjects seeking improvement of their skin quality
6. Subjects of any phototype and ethnicity
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 given their free, informed and expressed written consent
11. 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
12. 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
13. Subjects who, in the judgement of the investigator, are likely to be compliant during the study
14. Subjects willing and capable of following the study rules and a fixed schedule
15. 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
18 years

Sex
All

Key exclusion criteria
1. Subject with any systemic disorder or skin disease that would in any way confound the 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 a 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 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

Date of first enrolment
15/08/2023

Date of final enrolment
19/09/2023

Locations

Countries of recruitment
France

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