ISRCTN49836437 https://doi.org/10.1186/ISRCTN49836437

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

Submission date
07/04/2021

Recruitment status
No longer recruiting

Registration date
12/04/2021

Overall study status
Completed

Last Edited
09/04/2021

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
Increasing numbers of people are seeking methods to counteract the ageing process. Higher patient expectations are increasing the demand to achieve a natural, rejuvenated and youthful appearance. Hyaluronic acid is a naturally occurring molecule present in the dermis (the thickest layer of the skin). Injecting a medical device gel containing hyaluronic acid helps to counteract the effects of ageing. The aim of this study is to evaluate the clinical performance and safety of a range of dermal fillers named Kysense® until 12 or 18 months after a single injection.

Who can participate?
People aged 18-65 seeking an improvement of their face

What does the study involve?
The study involves a single injection of Kysense dermal filler to treat one area of the face. Several follow-up visits at 1 month, 6 months, 12 months and 18 months will be carried out to assess the safety and performance of the injection.

What are the possible benefits and risks of participating?
The possible benefits are the rejuvenation of the treated area, improving self-esteem and self-confidence. Potential adverse events can occur. In most cases, those adverse events are naturally resolved within 1 week. In case of an adverse event persisting for more than 1 week, the investigator should assess and define the best course of actions.

Where is the study run from?
Eurofin Dermscan Pharmascan (France)

When is the study starting and how long is it expected to run for?
March 2021 to June 2023

Who is funding the study?
Kylane Laboratoires SA (Switzerland)

Who is the main contact?
Compliance@kylane.com

Contact information

Type(s)
Scientific

Contact name
Dr Basste Hadjab

Contact details
Chemin du pré-fleur 1-3
Plan Les Ouates
Switzerland
1228
+33 (0)601780449
b.hadjab@kylane.com

Additional identifiers

Protocol serial number
21E0717

Study information

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

Study objectives
The purpose of this clinical study is to evaluate the clinical performance and safety of the whole range of Kysense® products over a period of 12 or 18 months after a single injection in the context of a post market clinical study.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approval pending, CPP Nord-Ouest IV (Bâtiment ex-USNB, 6 rue du Professeur Laguesse, CHRU Lille, CS 70001, 59037 Lille Cedex; +33 (0)3 20 44 41 65; cppnordouestiv@univ-lille.fr), ref: 21.04.08.34903

Primary study design
Interventional

Study design
Open intra-individual single-dose single-center study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Moderate to severe peri-oral lines, moderate to severe nasolabial folds, moderate to severe cheeks/cheekbones volume deficit, chin recursion

Interventions
The objective of the study is to collect post-marketing data on the safety and effectiveness of the Kysense® range used on different facial injection sites. Four subgroups will be included in this study. The safety profile will be evaluated using the clinical evaluation of the injection site reaction and by collecting adverse events at different time points. The effectiveness will be assessed by evaluating the Global Aesthetic Improvement rated by the subject and independent assessor at different time points. Injectors satisfaction and illustration of the device effectiveness will be collected.

Intervention Type
Device

Phase
Phase IV

Drug/device/biological/vaccine name(s)
Kysense® range

Primary outcome(s)
The effectiveness of the Kysense® range used on different treated zones assessed using a clinical evaluation of the global aesthetic improvement (GAIS) rated by an independent assessor at 1 month (T1) after treatment

Key secondary outcome(s)
1. The effectiveness of the Kysense® range used on different treated zones assessed using a clinical evaluation of the global aesthetic improvement (GAIS) rated by an independent assessor at 6 months (T6), 12 months (T12) and 18 months (T18)
2. Safety assessed using clinical evaluation of the Injection Site Reactions (ISR) rated by the subject and the assessor, and by the collection of adverse events at T1, T6, T12 month + T18 month for a part of the population (groups 3 & 4)
3. Subject’s satisfaction and subject’s opinion on aesthetic improvement on the different treated zones using clinical evaluation of the global aesthetic improvement (GAIS) at T1, T6, T12 month + T18 months for a part of the population (groups 3 & 4)
4. The injector's satisfaction with the injection quality measured using a subjective evaluation questionnaire at the injection visit
5. Device effectiveness assessed using face macrophotographs at the injection visit, 1 month, 6 months, 12 months and 18 months if applicable

Completion date
05/06/2023

Eligibility

Key inclusion criteria
1. Subject seeking an improvement of her/his face aspect with HA filler
2. For group 1: Subject with moderate to severe peri-oral lines (score 3 to 5 on Bazin Upper lip scale)
3. For group 2: Subject with moderate to severe nasolabial folds (score 3 to 4 on WSRS scale)
4. For group 3: Subject with moderate to severe cheeks/cheekbones volume deficit (score 3 to 4 on Ascher lipoatrophy scale)
5. For group 4: Subject seeking improvement of chin retrusion
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 4 weeks and during all the study

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

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 4500 euros indemnities for participation in research involving human beings in the 12 previous months, including participation in the present study
6. Subject enrolled in another study or which exclusion 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 a known history of or suffering from autoimmune disease and/or immune deficiency
10. Subject suffering from an active disease such as inflammation, infection, tumours, inflammatory and/or infectious cutaneous disorders (herpes, acne, rosacea, porphyria) in the 6 months before the screening visit. Subjects with a history of herpes are not eligible even if asymptomatic at the time of inclusion

11. Subject with a history of streptococcal disease or an active streptococcus infection
12. Subject prone to develop inflammatory skin conditions or having a tendency to bleeding disorders
13. Subject predisposed to keloids or hypertrophic scarring or having healing disorders
14. Subject with a history of severe allergy or anaphylactic shock including known hypersensitivity to one of the ingredients of the investigational device (i.e. hyaluronic acid), to antiseptic solution or to amide-type anaesthetics

Relating to previous or ongoing treatment:
15. Any medication which may interfere, at the interpretation of the investigator, with the study objectives
16. Subject having received treatment with a laser, dermabrasion, surgery, 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
17. 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., hyaluronic acid, CaHA) or neurotoxin on or near the treated zone
18. Subject having received at any time or plans to receive during the study a permanent filler (e. g., polylactic acid, PMMA, silicone) on the face
19. Subject with subcutaneous retaining structure on the face (meshing, threads, gold strand)
20. 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
21. Subject undergoing a topical treatment on the test area or a systemic treatment:
21.1. Anti-inflammatory medication and/or antihistamines within the past 2 weeks and during the study
21.2. Corticosteroids within the past 2 weeks and during the study
21.3. Retinoids and/or immunosuppressors within the past 3 months and during the study

In terms of lifestyle:
22. Intensive exposure to sunlight or UV rays within the previous month and/or foreseen during the study
23. Subject planning to change her/his life habits during the study
24. Excessive consumption of alcohol (more than two glasses of wine per day) and/or tobacco (more than 10 cigarettes per day)

Date of first enrolment
05/06/2021

Date of final enrolment
30/09/2021

Locations

Countries of recruitment
France

Study participating centre

Eurofin Dermscan Pharmascan
114 boulevard du 11 novembre 1918
Villeurbanne
France
69100

Sponsor information

Organisation
Kylane Laboratoires SA

Funder(s)

Funder type
Industry

Funder Name
Kylane Laboratoires SA

Results and Publications

Individual participant data (IPD) sharing plan
Since the study will be carried out in France, the French requirements provided by the competent authority (CNIL) have to be followed. The researchers have obtained the authorization to collect data for the trial from this competent authority. The data recorded are data to characterize the trial population (birth date, gender and initials) and the assessment data performed at different timepoint. A consent form has to be obtained prior to starting the treatment. The name and surname will be anonymized by using reporting the initials on the CRFs. The data will be stored in the Trial Master File in a paper version and will not be shared with the public. These data can be checked by the competent authority upon request and will be made available within 5 business days.

IPD sharing plan summary
Other