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A study to assess the safety and efficacy of hyaluronic acid dermal fillers in the treatment of facial aging

Submission date
08/07/2022

Recruitment status
No longer recruiting

Registration date
11/07/2022

Overall study status
Completed

Last Edited
11/07/2022

Condition category
Skin and Connective Tissue Diseases

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

Plain English summary of protocol

Background and study aims
Hyaluronic acid dermal fillers are designed to restore volume to the face that has been lost through the ageing process and provide the patient with a more youthful appearance, The aims of the study are to generate a clinical data set to demonstrate the efficacy and safety of two hyaluronic acid dermal fillers when used to treat ageing in different areas of the face.

Who can participate?
Eligible subjects include female or male subjects between the ages of 25 and 65 years of age inclusively across a range of Fitzpatrick skin types.
If subjects meet the inclusion criteria, they have the option to receive injections in multiple treatment areas and generate data for more than one treatment indication.

What does the study involve?
The study is a 24-month, open-label, prospective, post-market clinical follow-up trial (PMCF), with two treatment groups. One group will receive the MaiLi Volume, another group will receive the MaiLi Extreme.
In the MaiLi Volume treatment arm, 30 subjects will be assigned for treatment of mid-face volume deficit and 36 subjects of temple hollowing. In the MaiLi Extreme treatment arm, 30 subjects will be assigned of treatment of mid-face volume deficit, 36 subjects of jawline ptosis, and 36 subjects of chin retrusion.
The study will be conducted in 4 European study sites, located in Belgium and Germany. The study consists of 5 visits to assess efficacy at month 3, month 6, month 12, month 18, and month 24. And consists of 6 visits to assess safety at week 2, month 3, month 6, month 12, month 18, and month 24.

What are the possible benefits and risks of participating?
Benefits: The information obtained during a trial may contribute to a better understanding of the use of the MaiLi medical devices in daily practice or to the development of new medical devices for the treatment of patients. The MaiLi medical devices may be beneficial in treating your facial volume loss and correcting the signs of ageing

Risks: Participation in a trial involves some risk. The use of hyaluronic fillers such as MaiLi Volume and MaiLi Extreme fillers can have side effects. Previous studies have shown that MaiLi Volume and MaiLi Extreme fillers were normally well tolerated, however, subjects mays still experience side effects.

Where is the study run from?
Sinclair Pharmaceuticals Ltd (UK)

When is the study starting and how long is it expected to run for?
October 2021 to June 2025

Who is funding the study?
Sinclair Pharmaceuticals Ltd (UK)

Who is the main contact?
Dr Stuart Boothman, sboothman@sinclairpharma.com

Contact information

Type(s)
Public

Contact name
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil Known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CS-21-03

Study information

Scientific Title

A Post Market Clinical Follow Up (PMCF) Study to Assess the Safety and Efficacy of MaiLi Volume and MaiLi Extreme in the Treatment of Temporal Hollowing, Mid-Face Volume Deficit, Jawline Ptosis, and Chin Retrusion

Study objectives
The purpose of the study is to generate a clinical data set to demonstrate the efficacy and safety of:
• MaiLi Volume as a treatment for mid-face volume deficit and temporal hollowing
• MaiLi Extreme as a treatment for mid-face volume deficit, jawline ptosis and chin retrusion

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 20/05/2022, EC UZ Brussel Commissie Medische Ethiek (Laarbeeklaan 101, 1090 Brussels, Belgium; + 32 2 477 55 84; commissie.ethiek@uzbrussel.be), ref: EC-2022-068; BUN: 1432022000051
2. Approved 20/05/2022, Ethisch Comité UZA/UAntwerpen (UZA, Drie Eikenstraat 655, B-2650 Edegem, Belgium; +32 3 821 38 97; ethisch.comite@uza.be), ref: Project ID 3042; Edge 002231; BUN B3002022000022
3. Approval pending, Ethikkommission der LMU München (Pettenkoferstr. 8a, D-80336 München, Germany; +49 (0)89 440055191; Ethikkommission@med.uni-muenchen.de), ref: 22-0344 fed

Study design
Multicentre interventional unblinded trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Facial aging including temporal hollowing, mid face volume deficit, jawline ptosis and chin retrusion

Interventions
There are 2 treatment groups, the MaiLi Volume and the MailLi Extreme groups. Participants in the MaiLi Volume group will receive treatment in the mid-face and/or temples, will participants in the MaiLi Extreme will receive treatment in the mid-face and/or jawline and/or chin. Both treatment groups will received a single treatment session will return for visits at 3, 6, 12, 18 and 24 months for assessment of treatment safety and efficacy.

Intervention Type
Supplement

Primary outcome(s)
1. Evaluate the proportion of subjects with an improvement (score of 3 and above) at 6 months in the Global Aesthetic Improvement Scale (GAIS) with assessments of:
• MaiLi Volume as a treatment for mid-face volume deficit and temporal hollowing.

• MaiLi Extreme as a treatment for mid-face volume deficit, jawline ptosis and chin retrusion. as determined by an on-site live independent evaluator.
2. Evaluate safety through the collection of all adverse events, inclusive of Serious Adverse Events (SAE), unanticipated problems
3. Unanticipated Adverse Device Effects (UADE), experienced in the post-treatment follow-up period.

Key secondary outcome(s))
1. The proportion of subjects with an improvement (score of 3 and above) in Global Aesthetic Improvement Scale (GAIS) assessments of the i) mid-face and ii) jawline and iii) chin area and iv) temple at 3, 12, 18 and 24 months by an on-site live independent evaluator.
2. The proportion of subjects with an improvement (score of 3 and above) in Global Aesthetic Improvement Scale (GAIS) assessments of the i) mid-face and ii) jawline iii) chin area and iv) temple at 3, 6, 12, 18 and 24 months by the subject.
3. The proportion of subjects exhibiting an improvement of ≥ 1 point from baseline on the mid-face volume deficit scale at 3, 6, 12, 18 and 24 months as rated by a blinded independent evaluator.
or
The proportion of subjects exhibiting an improvement of ≥ 1 point from baseline on the scale for the assessment of jawline sagging at 3, 6, 12, 18 and 24 months as rated by a blinded independent evaluator.
or
The proportion of subjects exhibiting an improvement of ≥ 1 point from baseline on the chin retrusion assessment scale at 3, 6, 12, 18 and 24 months as rated by a blinded independent evaluator.
or
The proportion of subjects exhibiting an improvement of ≥ 1 point from baseline on the temporal hollowing assessment scale at 3, 6, 12, 18 and 24 months as rated by a blinded independent evaluator.
4. Subject and investigator treatment satisfaction will be assessed by questionnaire at 3, 6, 12, 18 and 24 months

Completion date
01/06/2025

Eligibility

Key inclusion criteria
1. Subjects must be generally healthy and 25-65 years of age at Screening Visit
2. Subjects who have:
2.1. Mild to significant volume deficit in the mid-face (score of 2-4 on the designated photographic assessment scale)
or
2.2. Mild to moderate jawline ptosis (score of 1-2 on the designated photographic assessment scale)
or
2.3. Minimal to severe chin retrusion (score of 1-3 on the designated photographic assessment scale)
or
2.4. Minimal to severe temporal hollowing (score if 2-4 on the designated photographic assessment scale)

3. Subjects who are willing to provide written informed consent, including approval for facial photographs to be taken.
4. Subjects willing to commit to having no further facial aesthetic treatments (see Table 2), that could affect the appearance of the facial treatment area, for the duration of the study period, including follow-up.
5. Subjects must be willing and able to comply with protocol requirements, instructions, and protocol-stated restrictions and be likely to complete the study as planned.
6. Female of childbearing potential should use a medically accepted contraceptive regimen since at least 12 weeks prior to study entry and during all the study.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
Subjects meeting any of the following criteria will be excluded from the study:
1. Subjects who, in the twelve months prior to their enrolment assessment had undergone:
1.1. cosmetic facial plastic surgery (other than rhinoplasty),
1.2. tissue grafting (e.g., fat injections),
1.3. tissue lifting implants (e.g., threads, barbs) or other implants,
1.4. augmentation with any permanent or semi-permanent filler (e.g., silicone, PMMA, PLLA) or temporary filler (e.g., Ha, CaHA, PCL)
1.5. neuromodulator injections,
1.6. mesotherapy,
1.7. resurfacing in the mid-face (e.g., laser, radio frequency, dermabrasion, or chemical peel) in the region of the face to be treated.
2. Subjects who have received other facial aesthetic procedures, that affects the appearance of the facial treatment, at any time during the study period.
3. Subjects currently enrolled in other clinical trials.
4. Subjects with facial hair as this could interfere with study evaluations.
5. Subject who had been deprived of their freedom by administrative or legal decision or who is under guardianship.
6. Subject is an employee of the aesthetic surgery department on the investigational site, the CRO or study sponsor.
7. Pregnant or nursing woman or planning a pregnancy during the study.
8. Subjects taking thrombolytics or anticoagulants.
9. Subjects with bleeding disorders.
10. Subjects with known hypersensitivities to hyaluronic acid, lidocaine, amide local anaesthetics or other components of the treatment.
11. Subjects with a history of severe allergy or anaphylactic shock.
12. Subjects with active (or a history of) autoimmune disease.
13. Subjects with porphyria.
14. Subjects with cutaneous disorders and areas affected by inflammation and/or infectious skin

problems (e.g., acne, herpes) at or near the treatment site.
15. Subjects with a tendency to form keloids, hypertrophic scars or any other healing disorders.
16. Subject with known history of precancerous lesions/skin malignancies.
17. Subjects must avoid receiving COVID-19 vaccination for the 14 days before and following injection.

Date of first enrolment
01/08/2022

Date of final enrolment
01/02/2023

Locations

Countries of recruitment
Belgium

Germany

Study participating centre
Dr. Samira Baharlou
Laarbeeklaan 101
Brussels
Belgium
1090

Study participating centre
Dr. Filip Thiessen
Beukenlaan 10B,
Antwerp
Belgium
2020

Study participating centre
Priv.-Doz. Dr. med. Gerd Gauglitz
Studienzentrum, Adolf-Fraaß-Straße 10a
Grünwald
Germany
82031

Study participating centre
Dr. Peter Weisenseel
Dermatologikum Hamburg, Stephanspl. 5,

Hamburg
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20354

Sponsor information

Organisation
Sinclair Pharmaceuticals Limited

Funder(s)

Funder type
Industry

Funder Name
Sinclair Pharmaceuticals Limited

Results and Publications

Individual participant data (IPD) sharing plan
Stored in non-publicly available repository
- Type of data: Patient health data.
- Repository name: eCRF of Inductive Quotient.
- Link: The link to the eCRF be provided as soon as it is final.
- Process requesting access: Access to the eCRF could be requested through Inductive Quotient. The access will only be given to the authorised people.
- Timing of availability: The eCRF will be available mid July for 24/7.
- Consent obtained: The consent of the patient will be obtained before any study related procedures and will be documented in the eCRF and medical records.
- Comments on data anonymisation: The pseudonymisation process is described in the ICF. The patient will get a patient number that will be used throughout the study. The investigator and his /her team will be the only ones able to link the patient number to the patient identity (with some exceptions described in ICH-GCP).
- Ethical or legal restrictions: We will work according to the ICH-GCP, ISO 14155:2020, and the study will only be initiated when EC approval is ready. In addition, legal agreements between the CRO - Inductive Quotient, and CRO - Sponsor are in place.

IPD sharing plan summary
Stored in non-publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?

Participant information sheet	Participant information sheet version 1.0	11/11/2025	11/11/2025	No	Yes
Protocol file		24/01/2022	11/07/2022	No	No