ISRCTN30768206 https://doi.org/10.1186/ISRCTN30768206

Clinical study of the safety and effectiveness of two hyaluronic acid injectable products (MaiLi Precise® and MaiLi Define®) as fillers in the treatment of lip thinness and wrinkles around the mouth

Submission date
28/03/2022

Recruitment status
No longer recruiting

Registration date
29/03/2022

Overall study status
Completed

Last Edited
30/09/2024

Condition category
Other

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Procedures on the lips have become increasingly common and their popularity has grown due to cultural trends and the association of lip appearance with both youth and beauty. Many patients desire lips filler injection to improve the fullness and definition of their lips. The aim of this study is to evaluate the effectiveness and safety of MaiLi Precise® and MaiLi Define® for lip augmentation and the correction of wrinkles around the mouth (perioral area).

Who can participate?
People aged 18-65 years seeking an improvement of their lip volume and/or their perioral area

What does the study involve?
Participants are randomly allocated to receive a single injection of MaiLi Precise® or MaiLi Define®. Several follow-up visits will be carried out at Day 14, 1 month, 6 months and 12 months after the treatment assess the safety and effectiveness of the injection.

What are the possible benefits and risks of participating?
The possible benefits are an aesthetic improvement by increasing the volume of lips and/or filling the perioral wrinkles. Potential adverse events can occur. In most cases, those adverse events are naturally resolved within 1 week. In case of an adverse event lasting for more than 1 week, the investigator should assess and define the best course of action.

Where is the study run from?
Cabinet renaissance of Dr Gianfermi (France)

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

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

Who is the main contact?
Stuart Boothman
SBoothman@sinclair.com

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
21E1105

Study information

Scientific Title
Clinical study of the safety and effectiveness of the use of MaiLi Precise® and MaiLi Define® in the treatment of lips and perioral area

Study objectives
MaiLi Precise® and MaiLi Define® induce a global aesthetic improvement of the treated area(s).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 25/03/2022, CPP Nord-Ouest II (Bâtiment pharmacie - Hôpital Nord - Place Victor Pauchet 80054 Amiens, France; +33 (0)3 22 66 85 43; cpp.nordouest2@chu-amiens.fr), ref: 21.04692.000042

Primary study design
Observational

Study design
Prospective open-label interventional intra-individual study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
For MaiLi Precise® treatment: very thin to thin lip volume and /or moderate to severe perioral wrinkles; for MaiLi Define® treatment: thin to moderate lip volume

Interventions
34 subjects will be included in group 1 and treated with MaiLi Precise®:
1. At least 12 will be treated for lip volume
2. At least 11 will be treated for lip definition
3. At least 11 will be treated in the perioral wrinkles

34 subjects will be included in group 2 and treated with MaiLi Define® for lip volume.

Only one injection session is planned. 2 ml maximum per area will be used by the injector. The subjects will be followed up for up to 12 months after treatment.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
MaiLi Precise®, MaiLi Define®

Primary outcome(s)
Aesthetic Improvement measured using the Global Aesthetic Improvement Scale (GAIS) evaluated by an independent live assessor 6 months after treatment (M6)

Key secondary outcome(s)
1. Aesthetic improvement measured using the Global Aesthetic Improvement Scale (GAIS) evaluated by a live assessor 1 month (M1) and 12 months (M12) after treatment
2. Aesthetic improvement measured using the Global Aesthetic Improvement Scale (GAIS) evaluated by the subjects at M1, M6 and M12
3. Subject's satisfaction measured using an in-house questionnaire at M1, M6 and M12
4. Injector satisfaction measured using an in-house questionnaire at M1
5. Improvement of treated areas measured using Rossi and Bazin scales evaluated by an assessor on photographs at M1, M6 and M12
6. Safety measured using injection site reactions (ISR) rated by a live assessor and by the subjects and by the collection of adverse events after treatment, at M1, M6 and M12

Completion date
01/10/2023

Eligibility

Key inclusion criteria
1. Sex: female or male
2. Age: between 18 and 65 years
3. Subject seeking an improvement of her/his lip volume and/or perioral area
4.1. For group 1: subject with very thin to thin lips volume (score 1 to 2 on Rossi scale) and /or subject with moderate to severe perioral wrinkles (score 2 to 6 on the Bazin scale)
4.2. For group 2: subject with thin to moderate lips volume (score 2 to 3 on Rossi scale)
5. Subject having given freely and expressly his/her informed consent
6. Subject willing to have photographs of the face taken and who are willing provide approval for the use of their study data and photographs in published literature
7. Subject willing and able to comply with study follow-up procedures and schedule
8. Subject affiliated to a health social security system
9. Females of childbearing potential should use a medically accepted contraceptive regimen for at least 12 weeks prior to study entry and during the study
10. Subject willing to commit to having no further facial aesthetic treatments below the zygomatic arch for the duration of the study period, including follow-up

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
All

Total final enrolment
68

Key exclusion criteria
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 is an employee of the investigational site, the CRO or the study sponsor
6. Subject with scar(s), mole(s) or anything on the studied zones which might interfere with the evaluation (tattoo, permanent make-up)
7. Subject with major dental problems
8. Subject under epidemiologic surveillance / in quarantine linked to the COVID-19 pandemic
9. Subject suffering from a severe or progressive disease or any other pathology that may

interfere with the evaluation of the study result and/or subject safety
10. Subject with a known history of or suffering from autoimmune disease and/or immune deficiency
11. Subject with porphyria
12. Subject with a known history of streptococcal disease (recurrent throat infections, acute rheumatic fever with or without cardiac involvement)
13. Subject suffering from active disease such as inflammation, infection, tumours, inflammatory and/or infectious cutaneous disorders (herpes, acne, rosacea) on or around the lips within 6 months of the study entry
14. Subject predisposed to keloids or hypertrophic scarring
15. Subject with a known bleeding disorder or is receiving medication that will likely increase the risk of bleeding during treatment
16. Subject with a known history of precancerous lesions/skin malignancies
17. Subject with hypersensitivity or with known allergy to: hyaluronic acid, lidocaine, amide-type local anaesthetics or to one of the components of the tested devices or antiseptic solution
18. Subject with a known history of severe allergy or anaphylactic shock
19. Subject having received any medication which may interfere, at the interpretation of the investigator, with the study objectives in terms of efficacy and safety
20. Subject having received treatment with a laser or UV, dermabrasion, surgery, deep chemical peeling or any other procedure based on active dermal response on/around the lips within the past 6 months
21. Subject received within the past 12 months hyaluronic acid injections (not including this study) on or around the lips
22. Subject received at any time permanent filler (e.g. polylactic acid, PMMA, silicone) on or around the lips
23. Subject received at any time a lip threading surgery
24. Subject received oral surgery (e.g. tooth extraction, orthodontia or implantation) within 6 weeks prior to study entry
25. Subject using medication such as aspirin, nonsteroidal anti-inflammatory drugs (NSAIDs), antiplatelet agents, thrombolytics or anticoagulants within one week prior to injection visit and 1 month after treatment
26. Subject having started or changed his/her oral contraceptive or any other hormonal treatment during 12 weeks prior to study entry

Date of first enrolment
25/04/2022

Date of final enrolment
01/10/2022

Locations

Countries of recruitment
France

Study participating centre
Cabinet renaissance
54 rue Voltaire
Levallois Perret

France
92300

Sponsor information

Organisation
Sinclair Pharma

ROR
https://ror.org/00ab7gt92

Funder(s)

Funder type
Industry

Funder Name
Sinclair Pharmaceuticals Limited

Results and Publications

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results		30/09/2024	30/09/2024	No	No