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Clinical study of the safety and effectiveness of the use of two hyaluronic acid injectable products (MaiLi Precise® and MaiLi Define®) in the treatment of facial skin depressions of the mid-face

Submission date
09/02/2022

Recruitment status
No longer recruiting

Registration date
16/02/2022

Overall study status
Completed

Last Edited
09/07/2024

Condition category
Skin and Connective Tissue Diseases

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

Plain English summary of protocol

Background and study aims
Tissue filling by means of injection of dermal fillers has been used for over 20 years. Dermal fillers are substances injected below the surface of the skin to generate volume by filling the injected area, thereby improving lines, wrinkles and folds to give the skin a smoother appearance. The increase in skin depressions on the face is also a known sign of the ageing process; treatment with dermal fillers can help correct this deficit. The aim of this study is to evaluate the effectiveness and safety of two of these products, MaiLi Precise® and MaiLi Define®, for the treatment of facial volume depressions.

Who can participate?
People aged 25-65 years seeking an improvement/filling of her/his nasolabial folds and/or tear trough and/or marionette lines

What does the study involve?
Participants receive a single injection of MaiLi Precise® or MaiLi Define®. Several follow-up visits at Day 14, 1 month, 6 months and 12 months after treatment will be carried out to 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 filling treated area(s). 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 action.

Where is the study run from?
1. Clinica Universidad de Navarra (Spain)

2. Clinica Dermomedic (Spain)
3. Instituto médico Ricart (Spain)

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

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

Who is the main contact?
John Meadows
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Contact information

Type(s)
Scientific

Contact name
Mr John Meadows

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Additional identifiers

Protocol serial number
21E1104

Study information

Scientific Title
Clinical study of the safety and effectiveness of MaiLi Precise® and MaiLi Define® in the treatment of facial skin depressions

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 03/02/2022, CEIm of Navarra (C/ Irunlarrea, 3, Recinto Hospitalario, Pabellón de Docencia, 31008 Pamplona – Navarra, Spain; +34 (0)848 422495; comite.etico.investigacion.clinica@navarra.es) ref: PI_2021/151

Primary study design
Interventional

Study design
Prospective open-label multicentre interventional intra-individual study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
For MaiLi Precise® treatment: mild to moderate nasolabial folds and/or subjects with mild to moderate tear trough. For MaiLi Define® treatment: moderate to severe nasolabial folds and/or moderate to severe marionette lines.

Interventions
Participants receive a single injection of MaiLi Precise® or MaiLi Define®.

34 will be included in group 1 and treated with MaiLi Precise®:
1. At least 15 will be treated on the nasolabial folds
2. At least 15 will be treated on the tear trough

34 will be included in group 2 and treated with MaiLi Define®:
1. At least 15 will be treated on the nasolabial folds
2. At least 15 will be treated on the marionette lines

Subjects may be treated and assessed in more than one facial area amongst its inclusion group if they meet the required inclusion criteria.

Several follow-up visits at Day 14, 1 month, 6 months and 12 months after treatment will be carried out to assess the safety and effectiveness of the injection.

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 WSRS, and/or Barton and/or MLGS 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
30/07/2023

Eligibility

Key inclusion criteria
1. Sex: female or male
2. Age: between 25 and 65 years
3. Subject seeking an improvement of her/his face aspect with hyaluronic acid filler product
4.1. For group 1: subject with mild to moderate nasolabial folds (score 2 to 3 on the Wrinkle Severity Rating Scale [WSRS]) and/or subjects with mild to moderate tear trough (score 1 to 2 on the Barton scale)
4.2. For group 2: subject with moderate to severe nasolabial folds (score 3 to 4 on the WSRS scale) and/or subjects with moderate to severe marionette lines (score 2 and 3 on the Marionette Lines Grading Scale (MLGS)
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. 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
9. Subjects willing to commit to having no further facial aesthetic treatments below the level of the eyes 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
25 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 in a social or sanitary establishment
3. Subject suspected to be non-compliant according to the investigator's judgment
4. Subject is an employee of the investigational site, the CRO or study sponsor
5. Subject with scar(s), mole(s) or anything on the studied zones which might interfere with the evaluation
6. 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
7. Subject with a known history of or suffering from autoimmune disease and/or immune deficiency
8. Subject with porphyria
9. Subject with a known history of streptococcal disease (recurrent throat infections, acute rheumatic fever with or without cardiac involvement)
10. Subject suffering from active disease such as inflammation, infection, tumours, inflammatory and/or infectious cutaneous disorders (herpes, acne, rosacea) on the face within 6 months of the study entry
11. Subject predisposed to keloids or hypertrophic scarring
12. Subject with a known bleeding disorder or is receiving medication that will likely increase the risk of bleeding during treatment
13. Subject with a known history of precancerous lesions/skin malignancies
14. 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
15. Subject with a known history of severe allergy or anaphylactic shock
16. Any medication which may interfere, at the interpretation of the investigator, with the study objectives in term of efficacy and safety
17. Subject having received treatment with a laser or UV, dermabrasion, surgery, deep chemical peeling or any other procedure based on active dermal below the level of the eyes within the past 6 months
18. Subject having received within the past 12 months hyaluronic acid injections (not including this study) below the level of the eyes
19. Subject having received at any time permanent filler (e.g. polylactic acid, PMMA, silicone) below the level of the eyes
20. Subject having received at any time threading surgery
21. 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
22. 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
01/03/2022

Date of final enrolment
01/07/2022

Locations

Countries of recruitment
Spain

Study participating centre
Clinica Universidad de Navarra
Av. de Pío XII, 36
Pamplona
Spain
31008

Study participating centre
Clinica Dermomedic
Calle de Jorge Juan, 36
Madrid
Spain
28001

Study participating centre
Instituto médico Ricart
Carrer de les Arts Gràfiques, Nº 5
València
Spain
46010

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
As sponsor, Sinclair have no wish or requirement for the participant-level dataset to be made available. They will only establish a global database with all participant data. Data will be kept by the study sites for 1 year after the end of the study, then data will be archived for 15 years by the 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		08/07/2024	08/07/2024	No	No