ISRCTN66942709 https://doi.org/10.1186/ISRCTN66942709

A study to assess the safety and efficacy of Poly-L-lactic acid dermal fillers in the treatment of facial ageing

Submission date
16/11/2022

Recruitment status
No longer recruiting

Registration date
01/12/2022

Overall study status
Completed

Last Edited
01/12/2022

Condition category
Other

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

Plain English summary of protocol

Background and study aims
Poly-L-lactic acid dermal fillers are designed to soften facial features and restore volume to the face that has been lost through the ageing process. This study will generate data concerning the long-term effects and safety of Sinclair's approved dermal filler product, Lanluma V, in the aesthetic treatment of a number of different facial features.

Who can participate?
Female or male subjects aged between 25 and 75 years old who opt to receive injections in multiple treatment areas and generate data for more than one treatment indication

What does the study involve?
Potential participants will be screened using Mid-face volume deficit (MFVD), Wrinkle Severity Rating Scale (WSRS), jawline ptosis and temporal hollowing scales. The study will be a 25-month, open-label, prospective, post-market clinical follow-up trial (PMCF). Participants will be assigned to one of the four treatment groups:
1. Mid-face
2. Jawline/Jowls
3. Nasolabial folds
4. Temples
Participants have the option to receive injections in multiple treatment areas. Therefore, data for more than one treatment indication may be generated from one participant.
The study consists of 2 visits on day 1 and in month 2 for treatment and 1 visit for an optional third treatment in month 4. There will be 6 visits to assess effectiveness and safety at month 2, month 4, month 6, month 12, month 18, and month 25. A safety phone call will be performed in week 2.

What are the possible benefits and risks of participating?
The expected benefit is a potential correction of age-related skin depression and volume loss in the region(s) of treatments. The study will help to accumulate data on the long-term safety and effectiveness of Lanluma V.

There are risks related to the administration procedure, including, but not limited to bruising, swelling, redness and infection. Participants may also experience hypersensitivity to Lanluma V.

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

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

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

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

Contact information

Type(s)
Principal investigator

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Additional identifiers

Protocol serial number
CS-21-06

Study information

Scientific Title
Clinical study to assess the safety and efficacy of Lanluma V in the treatment of mid-face volume deficit, nasolabial folds, jawline ptosis and temporal hollowing

Acronym
Fill-V

Study objectives
The aim of this study is to demonstrate the safety and efficacy of a poly-L-lactic acid dermal filler (Lanluma V) injectable as a CE-marked medical device in a representative study population and to collect further clinical data about its clinical performance.

The primary hypothesis is that the efficacy of Lanluma V will be evident at 6 months post-treatment, while the secondary hypotheses are that Lanluma V will be efficacious and safe over the entire study period.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 05/10/2022, HM Hospitales Medical Research Ethics Committee (CEIm) (Avenida Montepríncipe, 25, 28660 Boadilla del Monte, Madrid, Spain; +34 91 7089900; secretariaceic@mail.hmhospitales.com), ref: 22.07.2057-GHM

Primary study design
Interventional

Study design
Multicentre prospective open-label study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Facial ageing

Interventions
Study population: Male or female subjects between the ages of 25 and 75 years of age with one or more of the following changes:
1. Mild to significant facial volume deficit (mid-face area)
2. Moderate to severe nasolabial folds
3. Mild to moderate jawline ptosis
4. Minimal to severe temporal hollowing

Screening process: Potential participants will be screened using Mid-face volume deficit (MFVD), Wrinkle Severity Rating Scale (WSRS), jawline ptosis and temporal hollowing scales.

The treatment plan for the study will be as follows:
1. Injection of Lanluma V at baseline
2. Retreatment of Lanluma V at 2 months (following assessment of efficacy and safety)
3. Optional retreatment of Lanluma V at 4 months (following assessment of efficacy and safety). The decision on whether to perform the third treatment will be mutually agreed upon by both the investigator and the subject

Assessment schedule: Seven on-site visits and one phone call visit. During seven visits after the initial treatment, skin depression defects and the effect of treatment are assessed at various angles and documented using live GAIS evaluations and standardised photography. Pictorial examples of the grades of various validated scales used in the study are available for on-site reference. Satisfaction questionnaires for subjects and physicians are an integral part of this aesthetic study. The injection technique and obligatory preparation steps follow the IFU of the product.

Intervention Type
Device

Phase
Phase IV

Drug/device/biological/vaccine name(s)
Poly-L-lactic acid-based dermal filler

Primary outcome(s)
Improved aesthetics and correction of skin depressions and contour in the treated area(s) of the face measured using the Global Aesthetic Improvement Scale (GAIS) at 6 months

Key secondary outcome(s)

1. Improved aesthetics and correction of skin depressions of the treated area(s) of the face measured using the Global Aesthetic Improvement Scale (GAIS), mid-face volume deficit scale, and photographic scales for the assessment of nasolabial folds, photographic scales for the assessment of jawline sagging, photographic temporal hollowing assessment scale, as appropriate, at earlier (2 and 4 months) and later timepoints in months 6, 12, 18, and 25 after injections
2. Patient-reported satisfaction with the aesthetics and correction of skin depressions of the treated area(s) of the face measured using treatment satisfaction questionnaires at earlier (2 and 4 months) and later timepoints in months 6, 12, 18, and 25 after injections
3. Safety measured through the collection of adverse events (AEs) and injection site reactions (ISR) recorded in subject diaries at 2 weeks, and 2, 4, 6, 12, 18 and 25 months after injections

Completion date
30/04/2025

Eligibility

Key inclusion criteria
1. Male or female subjects between the ages of 25 and 75 years of age
2. Subject seeking an aesthetic improvement of her/his face with a poly-L-lactic acid dermal filler product
3. Any one or more of the following clinician-assessed criteria:
3.1. Mild to significant volume deficit in the mid-face (score of 2-4 on the designated photographic assessment scale)
3.2. Moderate to severe nasolabial folds (3-4 on the designated photographic assessment scale)
3.3. Mild to moderate jawline ptosis as assessed (score of 1-2 on the designated photographic assessment scale)
3.4. Minimal to severe temporal hollowing (2-4 on the designated photographic assessment scale)
4. Subject having given freely and expressly his/her informed consent
5. Subject willing to have photographs of the face taken and who is willing to provide approval for the use of their study data including photographs
6. 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.
7. Women of childbearing potential should be using a medically accepted contraceptive regimen for at least 12 weeks prior to study entry and over the entire study duration
8. Subjects willing to commit to having no further facial aesthetic treatments that will affect the appearance of the study treatment areas for the duration of the study period, including follow-up

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Sex

All

Key exclusion criteria

1. Subjects who, in the months prior to their enrolment assessment have undergone any of the following treatments in the facial region to be treated:
1.1. 3 months prior:
1.1.1. Mesotherapy
1.1.2. Resurfacing (e.g., laser, radio frequency, dermabrasion, or chemical peel)
1.2. 6 months prior:
1.2.1 Temporary filler (e.g., Ha, CaHA, PCL)
1.2.2. Neuromodulator injections
1.3. 12 months prior:
1.3.1. Cosmetic facial plastic surgery (other than rhinoplasty)
1.3.2. Tissue grafting (e.g., fat injections)
1.3.3. Tissue lifting implants (e.g., threads, barbs) or other implants
1.3.4. Augmentation with semi-permanent filler (e.g., PLLA)
2. Subjects who have received treatment with a permanent, silicone or PMMA filler in the region of the face to be treated
3. Subjects who have received any other facial aesthetic procedures that will affect the appearance of the region of the face to be treated, at any time during the study period
4. Pregnant women or nursing women or women planning to become pregnant during the study
5. Subject, who is likely to become pregnant during the course of the study, who is not using or has changed or started their medically accepted contraceptive regimen or any other hormonal treatment during the 12 weeks prior to study entry
6. Subject with a known history of, or susceptibility to, keloid formation or hypertrophic scarring
7. 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
8. Subject with scar(s), mole(s), tattoos, permanent make-up, facial hair, or anything in the studied zones which might interfere with the evaluation
9. Subject with a known history of or suffering from autoimmune disease and/or immune deficiency unless stable and controlled by medication and will not interfere, at the interpretation of the investigator, with the study objectives in terms of efficacy and safety
10. Subject with porphyria
11. Subject with a known history of streptococcal disease (recurrent throat infections, acute rheumatic fever with or without cardiac involvement)
12. Subject with a known history of precancerous lesions/skin malignancies
13. Subject with a known history of severe allergy or anaphylactic shock
14. Subject with a known bleeding disorder or is receiving medication that will likely increase the risk of bleeding during treatment
15. 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
16. Subject suffering from an active disease such as inflammation, infection, tumours, psoriasis, allergic edema, inflammatory and/or infectious cutaneous disorders (herpes, acne, rosacea...) on the face within 6 months of the study entry
17. Any medication which may interfere, at the interpretation of the investigator, with the study objectives in terms of efficacy and safety.
18. 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.
19. Subjects with a medical history showing sensitivity for reacting to the treatment
20. Subject with major dental problems or subject who received oral surgery (e.g., tooth

extraction, orthodontia, or implantation) within 6 weeks prior to study entry
21. Known allergies to product ingredients (Poly-L-lactic acid, carboxymethylcellulose, mannitol)
22. Subject in institutional care
23. Subject who is deprived of their freedom by administrative or legal decision or who is under guardianship

Date of first enrolment
04/11/2022

Date of final enrolment
31/03/2023

Locations

Countries of recruitment
Spain

Study participating centre
Especialidades Médicas
Centro Médico Habana 39
Madrid
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28036

Study participating centre
Ocean Clinic SL
Avda. Ramón y Cajal 7
Málaga
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Study participating centre
ClinDerma
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Study participating centre
Clinic Bascoy
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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
Patient health data will be stored in a non-publicly available repository (eCRF of CRO Dr. med. Kottmann: link to the eCRF to be provided). Access to the eCRF will be available by request through CRO Dr. med. Kottmann. The access will only be given to authorised people. The consent of the patient will be obtained before any study-related procedures and will be documented in the eCRF and medical records. 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 their team will be the only ones able to link the patient number to their identity (with some exceptions described in ICH-GCP). 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 - Dr. med. Kottmann, and CRO - Sponsor are in place.

IPD sharing plan summary
Stored in non-publicly available repository