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A clinical study to assess the safety and efficacy of poly-L-lactic acid dermal filler as a treatment for the rejuvenation of the upper arms

Submission date
12/03/2025

Recruitment status
No longer recruiting

Registration date
18/03/2025

Overall study status
Ongoing

Last Edited
18/03/2025

Condition category
Skin and Connective Tissue Diseases

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

Plain English summary of protocol

Background and study aims
The aim of this study is to demonstrate the effectiveness and safety of Lanluma V in the treatment of age-related sagging of upper arm skin. Poly-L-lactic acid dermal fillers are designed to restore volume that has been lost through the aging process and may be used in the correction of the loss of elasticity and firmness in the skin of the upper arm.

Who can participate?
Men and women aged between 40 and 65 years old

What does the study involve?
Participants receive Lanluma V injections and consent to generate a clinical dataset to demonstrate the effectiveness and safety of Lanluma V as a treatment for the rejuvenation of the upper arms. Physicians with longstanding experience in the aesthetic field perform the injections.
The study consists of two visits on day 1 and in month 2 for treatment and one visit for an optional third treatment in month 4. There will be six visits to assess effectiveness and safety at months 2, 4, 6, 12, 18, and 25. A safety follow-up visit and check of participant diaries is performed in week 2.

What are the possible benefits and risks of participating?
There are risks related to the administration procedure per se (irrespective of the filler), including but not limited to bruising, swelling, redness, and infection. On rare occasions participants may experience hypersensitivity to Lanluma V.

Where is the study run from?
1. García Clínicas Dr. Jorge García (Spain)
2. Clínica de Medicina Estética Dra. Páez (Spain)

When is the study starting and how long is it expected to run for?
September 2022 to December 2025

Who is funding the study?
Sinclair Ltd (UK)

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

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Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CS-21-06

Study information

Scientific Title
A post-market follow-up study to assess the safety and efficacy of Lanluma V as a treatment for the rejuvenation of the upper arms

Study objectives
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
Ethics approval required

Ethics approval(s)
Approved 15/09/2022, CEIm de las Áreas de Salud Valladolid (Hospital Clínico Universitario de Valladolid, Facultad de Medicina, Farmacología, Valladolid, 47005, Spain; +34 (0)983 423077; jalvarezgo@saludcastillayleon.es), ref: EOm 22-400

Study design
Multicentre prospective open-label (non-randomized) interventional post-market clinical follow-up (PMCF) study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)

Treatment

Participant information sheet
Not available in web format

Health condition(s) or problem(s) studied
Ageing of the skin

Interventions
Lanluma V is a CE-marked medical device and is used within its intended use. Injection of Lanluma V at baseline is followed by retreatment at 2 months (following assessment of efficacy and safety) and an optional retreatment at 4 months.

During seven visits on site after the initial treatment, skin depression defects and the effect of treatment are assessed and documented using live GAIS evaluations and standardised photography. There is one phone call visit after the initial treatment.

Participants and physicians fill in satisfaction questionnaires. Safety data will be collected for up to 25 months.

Intervention Type
Device

Pharmaceutical study type(s)
Not Applicable

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Lanluma V

Primary outcome measure
The proportion of participants (%) with an improvement (i.e., improved, much improved or very much improved) over baseline at 6 months in Global Aesthetic Improvement Scale (GAIS) assessments in the treated region(s) of the upper arm, as assessed by an on-site independent evaluator

Secondary outcome measures
1. The proportion of participants (%) with an improvement (i.e., improved, much improved or very much improved) over baseline in Global Aesthetic Improvement Scale (GAIS) assessments of the treated upper arm at 2, 4, 12, 18 and 25 months, as assessed by an on-site independent evaluator and participant
2. The proportion of participants (%) exhibiting an improvement of ≥1 point from baseline on a photographic Arm Visual Analog scale at 2, 4, 6, 12, 18 and 25 months as assessed by a blinded remote independent evaluator
3. Treatment satisfaction based on questionnaires filled by the participants (at 2, 4, 6, 12, 18 and 25 months) and the investigators (straight after treatment)

Overall study start date
15/09/2022

Completion date
12/12/2025

Eligibility

Key inclusion criteria
1. Subjects with type II or type III upper arms on the Arm Visual Analog Scale (Arm VAS) seeking treatment for rejuvenation of the upper arms
2. Female and male subjects between 40-65 years of age
3. Subjects who are willing to provide written informed consent including approval of the use of their data and photographs in this study and any subsequent publications or presentations
4. Subjects willing to commit to having no further aesthetic treatments, such as body contouring procedures, for the duration of the study period
5. Subjects willing to commit to having no further tattoos on the upper arms for the duration of the study period
6. Women of childbearing potential should use a medically accepted contraceptive regimen since at least 12 weeks prior to study entry and during the entire study

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
40 Years

Upper age limit
65 Years

Sex
Both

Target number of participants
72

Total final enrolment
72

Key exclusion criteria
1. Subjects who, in the 12 months prior to their enrolment assessment have undergone in the region of the upper arms:
1.1. Tissue grafting (e.g. fat injections)
1.2. Lipolysis
1.3. Tissue lifting implants (e.g. threads, barbs) or other implants
1.4. Augmentation with any permanent or semipermanent filler (e.g. silicone, PMMA, PLLA)
1.5. Temporary dermal filler injections (e.g., HA, CaHA, PCL)
1.6. Neuromodulator injections
1.7. Mesotherapy
1.8. Resurfacing (laser, radio frequency, dermabrasion, or chemical peel)

2. Subjects who have received treatment with a permanent filler (e.g. silicone, PMMA, PLLA) in the region of the upper arms
3. Subjects who have received any other aesthetic procedures in the region of the upper arms at any time during the study period
4. Subject who had been deprived of their freedom by administrative or legal decision or who is under guardianship
5. Subject is an employee of the aesthetic surgery department on the investigational site, the Clinical Research Organisation (CRO) or the study sponsor
6. Subjects who in the opinion of the investigator are unsuitable to take part in the study for scientific or medical reasons
7. Subjects currently enrolled in other clinical trials
8. Excessive skin laxity in the region of the upper arms
9. Subjects who, if female, are pregnant or plan to become pregnant during the study period
10. Subjects with known allergies to the product ingredients (i.e. poly-L-lactic acid (PLLA), sodium carboxymethyl cellulose (CMC), Mannitol)
11. Subjects must avoid receiving a Coronavirus Disease (COVID)-19 vaccination for the 14 days before and following the injection
12. Subject with a cutaneous disorder, inflammation, infection, significant scarring, open wounds, lesions or tattoos in the region of the upper arms
13. Subjects taking thrombolytics or anticoagulants
14. Subjects with bleeding disorders
15. Subjects with a history of severe allergy or anaphylactic shock
16. Subjects with active (or a history of) autoimmune disease
17. Subjects with porphyria
18. Subjects with a tendency to form keloids, hypertrophic scars or any other healing disorders
19. Subjects with a history of lymphedema in the arms

Date of first enrolment
13/01/2023

Date of final enrolment
08/05/2023

Locations

Countries of recruitment
Spain

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Study participating centre

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Sponsor type
Industry

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Funder(s)

Funder type
Industry

Funder Name
Sinclair Ltd

Results and Publications

Publication and dissemination plan
planned publication in a peer-reviewed journal

Intention to publish date
01/12/2026

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are not expected to be made available due to commercial sensitivities.

IPD sharing plan summary

Not expected to be made available