

A study to assess the safety and efficacy of poly-L-lactic acid dermal filler in the enhancement of buttocks and treatment of cellulite

Submission date 12/03/2025	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 12/03/2025	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 14/11/2025	Condition category Skin and Connective Tissue Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input checked="" type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

The purpose of the clinical investigation is to assess the safety and effectiveness of poly-L-lactic acid dermal fillers in buttock augmentation and the treatment of buttock/thigh cellulite. Poly-L-lactic acid dermal fillers are designed to restore skin volume and improve skin texture and are used to reshape contours and reduce flaccidity.

Who can participate?

Men and women aged between 25 and 50 years old

What does the study involve?

Participants receive poly-L-lactic acid injections. The study consists of a screening visit which can take place up to 14 days before treatment on Day 0 or alternatively, the screening visit and baseline treatment can both take place on day 0. Treatment will also be performed at the month 2 visit and an optional third treatment at month 4. There will be six visits to assess effectiveness and safety at months 2, 4, 6, 12, 18, and 25. A safety 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 X. The study will help to accumulate data on the long-term safety and effectiveness of Lanluma X.

Where is the study run from?

1. Dr. Kai O. Kaye (Spain)
2. Dr. Pilar de Frutos (Spain)

When is the study starting and how long is it expected to run for?

October 2021 to September 2025

Who is funding the study?
Sinclair Ltd (UK)

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

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Protocol serial number

CS-21-05

Study information

Scientific Title

A post-market follow-up study to assess the safety and efficacy of Lanluma X in the enhancement of buttocks and treatment of cellulite

Study objectives

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

Ethics approval required

Ethics approval required

Ethics approval(s)

approved 15/12/2022, Consejería De Salud Y Consumo (Avenida De La Innovación, Edificio Arena 1, Sevilla, 41020, Spain; +34 (0)955 00 63 00; consejera.csc@juntadeandalucia.es), ref: 202599900769088

Study design

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

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Enhancement of the volume of the buttocks and correction of skin depressions such as cellulite

Interventions

Poly-L-lactic acid dermal filler (Lanluma X) is a CE-marked medical device and is injected at baseline and 2 months (following assessment of efficacy and safety). There is an optional retreatment of Lanluma X at 4 months. There are seven follow-up visits to assess efficacy and safety: at week 2 (only safety), month 2 (prior to the second treatment), month 4 (prior to optional third treatment), months 6, 12, 18, and 25. At these visits, the effect of the treatment

will be assessed and documented using live GAIS evaluations, and standardised photography. Satisfaction questionnaires for subjects and study physicians are an integral part of this aesthetic study.

Intervention Type

Device

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Poly-L-lactic acid

Primary outcome(s)

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 of buttocks augmentation and/or cellulite appearance in buttocks/thighs, as assessed by an on-site independent evaluator

Key secondary outcome(s)

1. 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 of buttocks augmentation and/or cellulite appearance in buttocks/thighs at 2, 4, 12, 18 and 25 months, as assessed by an on-site independent evaluator and self-assessed by participants
2. The proportion of participants (%) exhibiting a reduction of ≥ 1 point from baseline in Clinician Reported Photonumeric Cellulite Severity Scale (CR-PCSS) for cellulite appearance in buttocks and/or thighs at 2, 4, 6, 12, 18 and 25 months as assessed by a blinded remote independent evaluator
3. Participant and Investigator treatment satisfaction based on questionnaires completed by the participants (at 2, 4, 6, 12, 18 and 25 months post-treatment) and the investigators (after treatment)

Completion date

24/09/2025

Eligibility

Key inclusion criteria

1. Subjects who:
 - 1.1 Are seeking buttock augmentation
And/or
 - 1.2. Are seeking treatment for reduction of mild to moderate (2-3) cellulite in the region of the buttocks and/or the back of the thighs when assessed using the Clinician Reported Photonumeric Cellulite Severity Scale (CR-PCSS)
2. Female and male subjects aged 25-50 years of age
3. Body mass index ≤ 30 kg/m²
4. 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
5. Subjects willing to commit to having no further aesthetic treatments in the buttocks and thighs, such as body contouring procedures, for the duration of the study period

6. Subjects willing to commit to having no further tattoos on the buttocks and thighs for the duration of the study period

7. Females 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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

25 years

Upper age limit

50 years

Sex

All

Total final enrolment

73

Key exclusion criteria

1. Subjects meeting any of the following criteria will be excluded from the study: subjects who, in the months prior to their enrollment assessment, have undergone any of the following treatments in the buttocks and thighs:

3 months prior:

- Mesotherapy
- Resurfacing (e.g., laser, radio frequency, dermabrasion, or chemical peel)

6 months prior:

- Temporary filler (e.g., Ha, CaHA, PCL)
- Neuromodulator injections

12 months prior:

- Cosmetic plastic surgery in the area to be treated
- Tissue grafting (e.g., fat injections)
- Tissue lifting implants (e.g., threads, barbs) or other implants
- Augmentation with semi-permanent filler (e.g., PLLA)

2. Previous augmentation with any permanent filler in the region of the buttocks or thighs

3. Subjects who have received any other aesthetic procedures in the region of the buttocks or thighs 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 Contract Research Organisation (CRO) or 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 subcutaneous fat in the region of the buttocks and thighs
9. Excessive skin laxity in the region of the buttocks and thighs
10. Subjects who, if female, are pregnant or plan to become pregnant during the study period
11. Subjects with known allergies to the product ingredients (i.e. Poly-L-lactic Acid (PLLA), sodium carboxymethyl cellulose (CMC), Mannitol)
12. Subjects must avoid receiving a Coronavirus Disease (COVID) -19 vaccination for the 14 days before and following the injection.
13. Subjects with a cutaneous disorder, inflammation, infection, significant scarring, open wounds, lesions or tattoos in the region of the buttocks and thighs
14. Subjects taking thrombolytics or anticoagulants
15. Subjects with bleeding disorders
16. Subjects with a history of severe allergy or anaphylactic shock
17. Subjects with active (or a history of) autoimmune disease
18. Subjects with porphyria
19. Subjects with a tendency to form keloids, hypertrophic scars or any other healing disorders

Date of first enrolment

13/01/2023

Date of final enrolment

08/05/2023

Locations

Countries of recruitment

Spain

Study participating centre

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Study participating centre

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Sponsor information

Organisation

Sinclair Pharmaceuticals Ltd

Funder(s)

Funder type

Industry

Funder Name

Sinclair Ltd

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not expected to be made available