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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	Recruitment status	[_] Prospectively registered
12/03/2025	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
12/03/2025	Ongoing	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
12/03/2025	Skin and Connective Tissue Diseases	[X] 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 November 2025

Who is funding the study?
Sinclair Ltd (UK)

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

Contact information

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Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Non randomised study

Study setting(s)
Other therapist office

Study type(s)

Treatment

Participant information sheet
Not available in web format

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

Pharmaceutical study type(s)
Not Applicable

Phase
Not Applicable

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

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 of buttocks augmentation and/or cellulite appearance in buttocks/thighs, 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 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)

Overall study start date

01/10/2021

Completion date
15/11/2025

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

Age group
Adult

Lower age limit
25 Years

Upper age limit
50 Years

Sex
Both

Target number of participants
72

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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Sponsor type
Industry

Website
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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
15/01/2027

Individual participant data (IPD) sharing plan
There are no plans to make available the raw data to the scientific community.

IPD sharing plan summary
Not expected to be made available