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A post-market clinical follow-up study of Perfectha Subskin Lidocaine

Submission date
22/11/2022

Recruitment status
No longer recruiting

Registration date
24/11/2022

Overall study status
Completed

Last Edited
04/06/2025

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
The facial morphology from infancy to old age is a complex, three-dimensional (3D) interplay of multiple structural tissue layers, and our understanding of this process is in a constant state of evolution and refinement1. At this time, facial aging research is defining the basic changes that occur in specific tissues, but it is how these changes affect what is observed in the aging face that remains to be defined. Cumulative changes over time in all structural tissue layers of the face lead to a change in the morphology of the entire face in terms of shape, proportions, and topography. Those changes in facial topography with aging sharpen the once smooth transition between anatomic units.
The skin of the face has consistent attachment points to the underlying structures through the facial retaining ligaments, and as the volume of the face deflates, these attachment points will define most of the shadows that develop with age. In youth, the 3D-surface contours of the face predominantly reflect light. Volume changes over time result in broken reflections with intervening shadows. This concept is critical to our understanding because seemingly subtle changes in light and shadow over time can have an enormous impact on our perception of a face in an almost indiscernible way. Moreover, the integration of volume replacement into the surgical and non-surgical therapeutic algorithm as a treatment for volume loss during aging is probably the most important recent development in the field of facial rejuvenation.
The study aims to generate a coherent clinical data set to demonstrate the efficacy and safety of Perfectha Subskin Lidocaine as a treatment for significant loss of volume in the cheeks, jawline and/or chin.

Who can participate?
Male or female patients between the ages of 25 and 65 years of age inclusively across a range of Fitzpatrick skin types presenting significant loss of volume in the cheeks, jawline and/or chin can participate in this study.

What does the study involve?
The injection will be administered slowly into the deep subcutaneous fat tissue and/or into the supraperiostic zone in the appropriate area of the face by a well-trained physician. The injection volume of Perfectha Subskin Lidocaine will vary, depending on the required area of treatment and level of correction. However, the injection volume will not exceed 3 mL per area (consider

left and right as separate areas.
The study consists of 6 visits to assess efficacy and safety at month 1, month 3, month 6, month 9, month 12, and month 18. At week 2, a phone call will be made between the investigator and subject to discuss whether any (Serious) Adverse Events ((S)AEs) have occurred in the two weeks following treatment. If the subject receives the optional touch-up treatment at month 1 there will be an additional follow-up phone call at 6 weeks to assess safety only.

What are the possible benefits and risks of participating?
The expected benefits for subjects participating in this investigation is the aesthetic improvement by augmentation of the volume of the facial tissues and improvement of the facial contour. The Perfectha Subskin Lidocaine product modifies the anatomy and/or alleviates a physiological process at the level of the face.

As described above, the Perfectha Lidocaine product family consists of resorbable hyaluronic acid (HA) gel implants intended for reconstructive purposes. Preclinical testing in accordance with requirements of ISO10993 “Biological evaluation of medical devices” has been completed on Perfectha. As Perfectha and Perfectha Lidocaine contain the same constituents, apart from lidocaine hydrochloride, equivalent biocompatibility performance would be expected from Perfectha Lidocaine and Perfectha can be considered representative of Perfectha Lido. But with reduced pain following injection.
In the Perfectha Clinical Evaluation Report, all adverse events recorded in Perfectha studies performed to date were counted and divided by adverse event type. In a total number of 1,963 subjects, 403 AEs were recorded during Perfectha clinical trials.

The compliance of the risk analysis and the Instruction for Use (IFU) of Perfectha Subskin Lidocaine to the State-of-the-Art has been checked. The risks identified have all been mitigated to an acceptable risk level. For these risks, the benefit/risk ratio is considered acceptable for the use of Perfectha Subskin Lidocaine for the intended purpose as “reconstructive purpose in the treatment, for instance, of facial lipoatrophy, or morphological asymmetry associated with the aging process or other underlying conditions” and to specific intended uses of each device of the range, as long as users are appropriately warned of known limitations and risks associated with these devices.

Furthermore, the benefits of Perfectha Subskin Lidocaine outweigh the risks, as determined by the robustness of the effectiveness results, the lack of long-term sequelae, and the high subject satisfaction. No new risks have been identified by screening the international and national public databases, and do not need to be taken into consideration in the risk analyses of the Perfectha Subskin Lidocaine product. The risks of short-term adverse events outcomes seen after injection and rare adverse events are sufficiently well understood for subjects to make informed decisions about device use. Moreover, the Instruction for Uses (IFUs) correctly describe the indications of the Perfectha Subskin Lidocaine device as supported by sufficient clinical data.

If the subject has ever suffered from herpes infection, the risk of herpes reactivation following dermal filler injection has been reported to be about 1.5%.

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

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

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

Who is the main contact?
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Contact information

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Public

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil Known

Integrated Research Application System (IRAS)
323072

Protocol serial number
IRAS 323072

Study information

Scientific Title
A post market clinical follow up (PMCF) study to assess the safety and efficacy of use of Perfectha Subskin Lidocaine in the treatment of significant loss of volume in the cheeks, jawline and/or chin

Acronym
PMCFPSL

Study objectives
To generate a coherent clinical data set to demonstrate the efficacy and safety of Perfectha Subskin Lidocaine as a treatment for significant loss of volume in the cheeks, jawline and/or chin.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 22/12/2022, Health and Social Care Research Ethics Committee B (Business Services Organisation, Lissue Industrial Estate West, 5 Rathdown Walk, Moira Road, Lisburn, BT28 2RF, UK; +44 028 9536 1400; RECB@hscni.net)

Study design
Open-label prospective post-market clinical follow-up trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
A range of Fitzpatrick skin types presenting significant loss of volume in the cheeks, jawline and /or chin

Interventions

The injection will be administered slowly into the deep subcutaneous fat tissue and/or into the supraperiostic zone in the appropriate area of the face by a well-trained physician. The injection volume of Perfectha Subskin Lidocaine will vary, depending on the required area of treatment and level of correction. However, the injection volume will not exceed 3 mL per area (consider left and right as separate areas. The Instruction for Use (IFU) will include the use of the needle, the procedure of administration, the storage conditions and the waste disposal.

The test articles in this study:
Perfectha Subskin Lidocaine: cross-linked hyaluronic acid (HA) (20mg/mL) + 0.3% lidocaine hydrochloride + phosphate buffer saline (q.s. 1mL)

Day 1 – Baseline visit (incl. treatment administration)
The screening/enrolment activities and baseline/treatment activities may be carried out at the same visit or different visits (maximum allowed window: ± 14 days) due to timing considerations of the investigator and/or subject. If this window is exceeded, a, a repeat screening visit would be required.
During the screening/enrolment and baseline visit(s), the following actions will be taken:

Screening/Enrolment activities
• Signing the Informed consent form. This form must be signed before the treatments are administered. However, It is possible that this form is signed on a different date (but not sooner) than when the treatment takes place
• When signing the Informed Consent Form (ICF), the subject will be given the option to apply a black box over the eyes on the photographs that will be taken (if the independent evaluator will not be hindered to evaluate the treatment area(s) such as cheekbones and mid-face). In addition, the subject will be given the option to give consent to the use of the photos for the promotion of the study products.
• Screening according the inclusion and exclusion criteria.
• Analysing medical history.
• Physical examination: measuring the vital parameters (e.g. blood pressure, weight and height).
• Analysing prior or concomitant medications and/or treatments.
• A urine pregnancy test will be performed on potential childbearing women.

Baseline visit/treatment activities
• Photographing the face at different angles (i.e., full face, 45°(left and right), and 90°(left and right). The photographs on baseline visit needs to be taken before the treatment with Perfectha Subskin Lidocaine is administered. A black box will be placed over the eyes in the photograph if the subject has ticked this option when signing the Informed consent form. The photographs are taken with Canfield Scientific devices and training on the use of the photographic devices will be provided by them.
• Subject will be given a questionnaire to indicate their overall satisfaction with the appearance of the area(s) of the face that will be treated/
• Treating the subject. The specialised health practitioner will inject Perfectha Subskin Lidocaine into the specific area(s) of the face.
• Investigator will fill in the injection satisfaction questionnaire
• After the treatment the subject will be asked to score the maximum pain felt during injection using a 100 mm Visual Analogue Scale (VAS) for pain.
• The investigator will evaluate any injection site reactions as per the ISR table
• Subject will be given a blank diary/ISR form for the next period (Day 0 – Day 30) to self-record any AEs/ISRs that may occur

Week 2 – Safety Assessment Visit
• A safety assessment is performed by a phone call including the recording of any adverse events and injection site reactions.

Month 1 – Follow-up visit and/or optional second treatment
• Photographing the face at different angles (i.e., full face, 45° (left and right), and 90°(left and right). A black box will be placed over the eyes in the photograph if the subject has ticked this option when signing the Informed consent form.
• Subject will be given a questionnaire to indicate their overall satisfaction with the appearance of the treated area(s) of the face.
• A safety assessment is performed including the recording of any Adverse Events (AEs) and Injection Reactions (ISRs) from the subject diary (Day 0 –Day 30)/ISR form. The investigator will evaluate any ISRs before and after the optional touch-up treatment is administered (if applicable).
• Subject will return the completed subject diary (Day 0 – Day 30) and will be given a blank diary for the next period (Week 4 – 18 months) (see appendix 5, Table 10). If an additional treatment was received, a 30-day diary for recording ISRs will be provided and should be returned at the Month 3 visit.
• Subject and on-site live independent evaluator (I) will do a live assessment using the GAIS scale and the photographs taken at the baseline visit
• The subject will receive optionally second course of treatment (if deemed necessary by the investigator).
• Investigator will fill in the injection satisfaction questionnaire
• After the treatment the subject will be asked to score the maximum pain felt during injection using a 100 mm Visual Analogue Scale (VAS) for pain

(Optional) Week 6 – Safety Assessment Visit (second treatment subjects only)
• A safety assessment is performed by a phone call including the recording of any adverse events and injection site reactions (ISRs).

Month 3 till Month 18 Visits
In the period from month 3 to month 18 of the study, the following actions will be carried out:

On 6, 9, and 12:
• Photographing the face at different angles (i.e., full face, 45°(left and right), and 90°(left and right). A black box will be placed over the eyes in the photograph if the subject has ticked this option when signing the Informed consent form.
• Subject will be given a questionnaire to indicate their overall satisfaction with the appearance of the treated area(s) of the face
• Subject will return the (in)complete filled in subject diary (Week 4 – Month 18) and will be given a blank diary (Week 4 – Month 18)
• A safety assessment is performed including the recording of any Adverse Events (AEs) from the diary (Week 4 – Month 18) and assessment/review of injection site reactions (ISRs). If the patient diary is not brought to the visit, any AEs/ISRs should be recorded at the next follow-up visit. If the diary is lost, any AEs/ISRs should be tried to be recorded.
• Subject and on-site live independent evaluator (I) will do a live assessment using the GAIS scale and the photographs taken at the baseline visit

On month 3 and month 18:
• The same actions taken at the above timepoints.
• An assessment of the photographs will be made of any improvement in the face using appropriate assessment scale for the treated area(s), by a blinded remote independent

evaluator (II) (here: blinding means that the evaluator does not know at what time in the study period the photograph were taken).

(Optional) on month 3
• If the subject received the touch-up treatment at month 1, he/she will return the 30-day diary, next to the (in)complete filled in subject diary (Week 4 – Month 18) (see appendix 5, Table 10), to perform a safety assessment and record any AEs and/or ISRs

End of Study (EoS)/ Premature Discontinuation Visit
• The subjects will come to the Investigator's office.
• They will bring back their completed subject diary.
• Collection of the eventual Adverse Events (AEs), concomitant treatments, and Injection Site Reactions (ISRs).

Unscheduled/ Rescue treatment Visit
Subjects should receive prompt medical attention. Evaluation by an appropriate medical practitioner specialist could be necessary in case of an intravascular injection that should occur. In case of adverse device effect affecting subject well-being, the investigator is authorized to prescribe to the subject a rescue treatment. The adverse event (AE) will be recorded in the subject's electronic Case Report Form (eCRF) and source document, including details on rescue medication.

Intervention Type
Device

Phase
Phase III/IV

Drug/device/biological/vaccine name(s)
Perfectha Subskin Lidocaine

Primary outcome(s)
1. Global Aesthetic Improvement Scale (GAIS) assessments as rated by an on-site live independent evaluator at baseline and 3 months
In cases where more than one area is treated, the improvement relates to the primary treatment area. An independent GAIS score will be also recorded for each additional area in which the subject is injected to allow sub-group analysis of the GAIS score for each treatment area.
2. Adverse Events (AEs), inclusive of Serious Adverse Events (SAEs), Unanticipated Problems (UPs), and Unanticipated Adverse Device Effects (UADEs), experienced in the post-treatment follow-up period measured by monitoring throughout the invesigation.

Key secondary outcome(s))
To evaluate the efficacy of Perfectha Subskin Lidocaine through:
1. Improvement (score of 3 and above) in Global Aesthetic Improvement Scale (GAIS) assessments of the i) cheeks, (ii) jawline and/or iii) chin area at 1, 6, 9, 12, and 18 months post treatment by an on-site live independent evaluator.
2. Improvement (score of 3 and above) in Global Aesthetic Improvement Scale (GAIS) assessments of the i) cheeks, (ii) jawline and/or iii) chin area at 1, 3, 6, 9, 12, and 18 months post treatment by the subject.
3. Improvement of ≥ 1 point from baseline on the mid-face volume deficit scale at 1, 3, 6, 9, 12, and 18 months post treatment as rated by a blinded remote independent evaluator.

4. Improvement of ≥ 1 point from baseline on the scale for the assessment of loss of volume at the jawline sagging at 1, 3, 6, 9, 12, and 18 months post treatment as rated by a blinded remote independent evaluator.
5. Improvement of ≥ 1 point from baseline on loss of volume on the chin retrusion assessment scale at 1, 3, 6, 9, 12, and 18 months post treatment as rated by a blinded remote independent evaluator

6. Patient self-assessment of their overall satisfaction with the results of the treatment at 1, 3, 6, 9, 12, and 18 months post treatment.
7. Investigator satisfaction of the use of the medical device through an investigator satisfaction questionnaire.

Completion date
17/03/2025

Eligibility

Key inclusion criteria
1. Subjects between 25 and 65 years of age.
2. Subjects seeking an aesthetic improvement of volume loss in his/her cheeks, jawline and/or chin with hyaluronic acid dermal filler
3. Subjects who present significant loss of volume in the cheeks, jawline and/or chin as assessed by a suitable recognised photographic scale:
3.1. Mild to significant volume deficit in the mid-face (score of 2-4 on the designated photographic assessment scale, or
3.2. Mild to moderate jawline ptosis (score of 1-2 on the designated photographic assessment scale, or
3.3. Minimal to severe chin retrusion (score of 1-3 on the designated photographic assessment scale
4. Subjects who are willing to provide written informed consent, including approval for facial photographs to be taken.
5. Subjects willing to commit to having no further facial aesthetic treatments, that could affect the appearance of the facial treatment area, for the duration of the study period, including follow-up.
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. Female 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)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
25 years

Upper age limit
65 years

Sex
All

Total final enrolment
69

Key exclusion criteria
1. Subjects who, in the twelve months prior to their enrolment assessment have undergone:
1.1. cosmetic facial plastic surgery (other than rhinoplasty),
1.2. tissue grafting (e.g., fat injections),
1.3. tissue lifting implants (e.g., threads, barbs) or other implants,
1.4. augmentation with any semi-permanent filler (e.g., silicone, PMMA, PLLA) or temporary filler (e.g., Ha, CaHA, PCL)
1.5. neuromodulator injections,
1.6. mesotherapy,
1.7. resurfacing in the mid-face (e.g., laser, radio frequency, dermabrasion, or chemical peel) in the region of the face to be treated.
2. Subjects who have received a treatment with a permanent filler (e.g. silicone, PMMA, PLLA) in the region of the face to be treated.
3. Subjects who have received other facial aesthetic procedures (see Table 3), that affect the appearance of the facial treatment, at any time during the study period.
4. Subject is in institutional care.
5. Subject who had been deprived of their freedom by administrative or legal decision or who is under guardianship.
6. Subject is an employee of the aesthetic surgery department on the investigational site, the Clinical Research Organisation (CRO) or study sponsor.
7. Pregnant or nursing woman or a woman planning a pregnancy during the study.
8. Subject 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.
9. Subjects who in the opinion of the investigator are unsuitable to take part in the study for scientific or medical reasons.
10. Subject suspected to be non-compliant according to the investigator's judgment.
11. Subjects currently enrolled in other clinical trials.
12. Subjects with scar(s), mole(s), tattoo(s), semipermanent makeup or facial hair in the region to be treated as this could interfere with study evaluations.
13. 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.
14. Subject with known bleeding disorder or is receiving medication that will likely increase the risk of bleeding during treatment.
15. Subjects with a tendency to form keloids, hypertrophic scars or any other healing disorders.
16. Subject receiving medical treatment that reduces or inhibits liver metabolism (cimetidine, beta blockers)
17. Subject with epilepsy not controlled by treatment.
18. Subject with known history of streptococcal disease (recurrent throat infections, acute rheumatic fever with or without cardiac involvement).
19. Subject suffering from active disease/symptoms such as inflammation, infection, tumours, psoriasis, allergic oedema, inflammatory and/or infectious cutaneous disorders (e.g., herpes,

acne, rosacea) on the face within 6 months of the study entry.
20. Subjects with a history of any disease which may have resulted in changes to facial contour or oedema during the study period (e.g., facial psoriasis, herpes zoster).
21. Subject with known history of precancerous lesions/skin malignancies.
22. Any medication which may interfere, at the interpretation of the investigator, with the study objectives in term of efficacy and safety.
23. 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.
24. 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
25. Subjects with known hypersensitivities to hyaluronic acid, lidocaine, amide local anesthetics or other components of the treatment including avian proteins, feathers and egg products (hyaluronic acid).
26. Subjects with a history of severe allergy or anaphylactic shock.
27. Subjects with active (or a history of) autoimmune disease and immune deficiency.
28. Subjects with porphyria.
29. Subjects must avoid receiving Coronavirus disease (COVID)-19 vaccination for the 14 days before and following injection.

Date of first enrolment
20/02/2023

Date of final enrolment
05/07/2023

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
The Laser and Light Cosmetic Medical Clinic
1 Church Gate Mews
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United Kingdom
LE11 1TZ

Study participating centre
Smileworks Liverpool
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Sponsor information

Organisation
Sinclair Pharma

ROR
https://ror.org/00ab7gt92

Funder(s)

Funder type
Industry

Funder Name
Sinclair Pharma

Results and Publications

Individual participant data (IPD) sharing plan
The current data sharing plans for this study are unknown and will be available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other unpublished results			04/06/2025	No	No
Participant information sheet	version 1.0	08/08/2022	24/11/2022	No	Yes