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Clinical study of the safety and effectiveness of the use of a hyaluronic acid injectable product (Perfectha® Finelines Lidocaine) in the treatment of wrinkles around the eyes and mouth

Submission date
12/12/2022

Recruitment status
No longer recruiting

Registration date
21/12/2022

Overall study status
Completed

Last Edited
18/10/2024

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
Tissue filling by means of injection of dermal fillers has been used for over 20 years. Dermal fillers are substances injected below the surface of the skin to generate volume by filling the injected area, thereby improving lines, wrinkles and folds to give the skin a smoother appearance. The increase in skin depressions on the face is also a known sign of the ageing process; treatment with dermal fillers can help correct this deficit.
The sponsor of this study, Sinclair Pharmaceuticals Limited, develops, markets and distributes products for aesthetic facial and body treatment. Perfectha® Lidocaine is a range of four cross-linked Hyaluronic Acid (HA) gels (Finelines, Derm, Deep and Subskin). Lidocaine hydrochloride 0.3% (w/w) is integrated into the gels to reduce the sensation of pain during treatment.
The current post-market clinical investigation is designed to evaluate the effectiveness and safety of the product in the range with the smallest particle size, Perfectha® Finelines Lidocaine, on superficial lines and depressions.

Who can participate?
Subject aged 25-65 years seeking an improvement of her/his face aspect with hyaluronic acid filler product.

What does the study involve?
The study involves an injection of Perfectha® Finelines Lidocaine at the first visit after screening. Several follow-up visits at Day 14, 1 month, 3 months, 6 months and 9 months after treatment will be carried out to assess the safety and effectiveness of the injection. At the 1 month follow-up visit, a touch-up injection is possible.

What are the possible benefits and risks of participating?
The possible benefits are an aesthetic improvement by filling the treated area(s). Potential

adverse events can occur. In most cases, those adverse events are naturally resolved within 1 week. In case of an adverse event persisting for more than 1 week, the investigator should assess and define the best course of action.

Where is the study run from?
The private office of Dr Sarfati and Dr Radulesco in France

When is the study starting and how long is it expected to run for?
January 2022 to February 2024

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

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

Contact information

Type(s)
Scientific

Contact name
Mr Stuart Boothman

Contact details
Sinclair Pharmaceuticals Limited
Eden House
Lakeside Chester Business Park
Chester
United Kingdom
CH4 9QZ
+44 20 7467 6920
SBoothman@sinclair.com

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
22E0942

Study information

Scientific Title

Assessment of the safety and effectiveness of use of Perfectha® Finelines Lidocaine in the treatment of the periorbital and perioral wrinkles and tear troughs

Study objectives
Perfectha® Finelines Lidocaine induces a global aesthetic improvement of the periorbital and perioral wrinkles and tear troughs

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 23/11/2022, Comité de protection des personnes Nord-Ouest IV (Bâtiment ex USN B (RDC), 6, rue du Professeur Laguesse CHU LILLE CS 700001 59037 LILLE CEDEX, France; +33 3.20.44.41.65; cppnordouestiv@univ-lille.fr), ref: 2022-A01776-37

Study design
Prospective open label multicentre intra-individual study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Other

Study type(s)
Other

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied
Mild to moderate tear troughs, moderate to severe perioral wrinkles, shallow to deep periorbital wrinkles

Interventions
69 patients will be treated in total with Perfectha® Finelines Lidocaine:
At least 23 subjects will be treated in the tear troughs
At least 23 subjects will be treated in the perioral wrinkles
At least 23 subjects will be treated in the periorbital wrinkles
One patient can be treated in more than one indication

Each subject treated can be treated in marionette lines and/or tear troughs and/or perioral wrinkles at the first visit. A touch-up treatment can be done (not mandatory) 1 month after the initial treatment. Several follow-up visits at Day 14, 1 month, 3 months, 6 months and 9 months after treatment will be carried out to assess the safety and effectiveness of the injection.

Intervention Type

Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Perfectha® Finelines Lidocaine

Primary outcome measure
Aesthetic Improvement is measured using the Global Aesthetic Improvement Scale (GAIS) evaluated by an independent live assessor 3 months after treatment (M3).

Secondary outcome measures
1. Aesthetic Improvement is measured using the Global Aesthetic Improvement Scale (GAIS) evaluated by a live assessor 1 (M1), 6 (M6) and 9 months (M9) after treatment.
2. Aesthetic Improvement is measured using the Global Aesthetic Improvement Scale (GAIS) evaluated by the subjects at M1, M3, M6 and M9.
3. Subject satisfaction is measured using an internal questionnaire at baseline, M1, M3, M6 and M9.
4. Injector satisfaction is measured using an internal questionnaire at D0 and M1 after injection.
5. Improvement of tear troughs measured using Barton's scale is evaluated by a blinded independent assessor on photographs at baseline, M1, M3, M6 and M9.
6. Improvement of perioral wrinkles severity measured using the upper lip wrinkles scale from Bazin is evaluated by a blinded independent assessor on photographs at baseline, M1, M3, M6 and M9.
7. Improvement of crow’s feet wrinkles severity measured using the crow’s feet wrinkles Bazin scale is evaluated by a blinded independent assessor on photographs at baseline, M1, M3, M6 and M9.
7. Prodedural pain is measured by the subjects using a 0 to 10 points pain scale at D0 and M1 after injection.
8. Safety is measured using Injection Site Reactions (ISR) rated by a live assessor and by the subjects and by collection of adverse events after treatment, at M1, M3, M6 and M9.

Overall study start date
24/06/2022

Completion date
29/02/2024

Eligibility

Key inclusion criteria
1. Sex: female or male.
2. Age: between 25 and 65 years.
3. Subject seeking an improvement of her/his face aspect with Hyaluronic Acid filler product.
4. Subject with mild to moderate tear troughs (score 1 to 2 on the Barton scale) and/or Subject with moderate to severe perioral wrinkles (score 2 to 6 on the upper lip wrinkles Bazin scale). and /or Subject with shallow to deep crow’s feet wrinkles, also known as periorbital wrinkles (score 2 to 4 on the Lemperle periorbital lines scale)
5. Subject having given freely and expressly his/her informed consent and data privacy consent.
6. Subject willing to have photographs of the face taken and willing to provide approval for the

use of their study data and anonymized photographs in published literature.
7. Subject willing and able to comply with study follow-up procedures and schedule.
8. Subject affiliated to a health social security system.
9. Female of childbearing potential should use a medically accepted contraceptive regimen since at least 12 weeks prior to study entry and during all the study.
10. Subject willing to commit to having no further facial aesthetic treatments for the duration of the study period, including followup:
10.1. For the subjects treated in tear troughs, no treatment in the mid-face, tear troughs, periorbital lines below the eyes and nose area.
10.2. For the subjects treated in perioral wrinkles, no treatment in the nose, lips and perioral area.
10.3. For the subjects treated in periorbital wrinkles, no treatment in the periorbital, temples and nose area

Participant type(s)
Healthy volunteer

Age group
Adult

Sex
Both

Target number of participants
69

Key exclusion criteria
1. Pregnant or nursing woman or planning a pregnancy during the study.
2. Subject who had been deprived of their freedom by administrative or legal decision or who is under guardianship.
3. Subject in a social or sanitary establishment.
4. Subject is an employee of the investigational site, the CRO or study sponsor.
5. Subject with scar(s), mole(s) or anything on the studied zones which might interfere with the evaluation (tattoo, permanent make-up...).
6. For subjects treated in perioral wrinkles: subject with major dental problems or major dental procedure withing 6 weeks before screening visit or planned during the study.
7. Subject not eligible for scientific reasons at the interpretation of the investigator.
8. Subject under epidemiologic surveillance / in quarantine linked to the COVID-19 pandemic.
9. Subject having a medical history which may interfere, at the interpretation of the investigator, with the study objectives in term of effectiveness and safety.
10. 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.
11. Subject with known history of or suffering from autoimmune disease and/or immune deficiency.
12. Subject with uncontrolled epilepsy.
13. Subject with porphyria.
14. Subject with known history of streptococcal disease (recurrent throat infections, acute rheumatic fever with or without cardiac involvement).
15. Subject suffering from active disease such as inflammation, infection, tumours, inflammatory and/or infectious cutaneous disorders (recurrent herpes, acne, rosacea...) on or around the eyes and lips within 6 months of the study entry.

16. Subject predisposed to keloids or hypertrophic scarring.
17. Subject with known bleeding/clotting disorder or is receiving medication that will likely increase the risk of bleeding during treatment (taking thrombolytics, anticoagulants, aspirin, nonsteroidal anti-inflammatory drugs or vitamin C) during 10 days before each injection.
18. Subject with known history of precancerous lesions/skin malignancies on/around the eyes and lips.
19. Subject with hypersensitivity or with known allergy to: hyaluronic acid, lidocaine, local disinfectant containing quaternary ammonium salts, amide type local anaesthetics, avian proteins, feathers and egg or to one of the antiseptic solution.
20. Subject with known history of severe allergy or anaphylactic shock.
21. Subject having received any medication which may interfere, at the interpretation of the investigator, with the study objectives in term of effectiveness and safety.
22. Subject receiving medical treatment that reduces or inhibits liver metabolism (cimetidine, beta blockers).
23. Subject having received treatment with a laser or UV, dermabrasion, deep chemical peel, prolonged sun exposure or any other procedure based on active dermal response on/around the eyes and lips within the past 6 months.
24. Subject having received a surgery anywhere on the face within the past 6 months (12 months of washout are required for the cervicofacial lifting and rhinoplasty).
25. Subject having received within the past 12 months any hyaluronic acid filler treatment or having received at any time fillers of animal origin, implant containing a substance other than hyaluronic acid, permanent implants, autologous fat transfer or threading surgery:
25.1. For the subjects treated in tear troughs, in the mid-face, tear troughs, periorbital lines below the eyes and nose area.
25.2 For the subjects treated in perioral wrinkles, in the nose, lips and perioral area.
25.3. For the subjects treated in periorbital wrinkles, in the periorbital, temples and nose area.
Injection in the areas listed above, to gain access to other areas of the face, are also non-allowable.
26. Subject having started or changed his/her oral contraceptive or any other hormonal treatment during 12 weeks prior to study entry.

Date of first enrolment
01/02/2023

Date of final enrolment
31/05/2023

Locations

Countries of recruitment
France

Study participating centre
Center 01
Doctor Sarfati office
267 Avenue de la Victoire du 8 Mai 1945
TOULON
France
83000

Study participating centre
Center 2
Doctor Radulesco office
Pôle PROMOD
Hôpital La Conception
147 Boulevard Baille
MARSEILLE
France
13385

Sponsor information

Organisation
Sinclair Pharmaceuticals Limited

Sponsor details
Eden House
Lakeside Chester Business Park
Chester
England
United Kingdom
CH4 9QZ
+44 20 7467 6920
SBoothman@sinclair.com

Sponsor type
Industry

Website
https://sinclair.com/

Funder(s)

Funder type
Industry

Funder Name
Sinclair Pharmaceuticals Limited

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
30/12/2024

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available because this is not needed by the sponsor. The sponsor will only establish a global database with all participants data. Data will be kept by the site for 1 year after the end of the trial, then data will be archived for 15 years by a CRO's subcontractor

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results			18/10/2024	No	No