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Clinical study for the safety and effectiveness of the use of Perfectha® Derm lidocaine in the treatment of medium wrinkles

Submission date
08/11/2022

Recruitment status
No longer recruiting

Registration date
09/11/2022

Overall study status
Completed

Last Edited
16/05/2024

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
The aim of this study is to evaluate the effectiveness and safety of Perfectha® Derm Lidocaine for the reduction of medium lines and depressions such as nasolabial folds (lines that form from the bottom of the nose to the corners of the mouth) and marionette lines (lines that run vertically between the mouth and chin).

Who can participate?
Healthy people aged between 25 and 65 years with medium lines and depressions such as mild to moderate nasolabial folds and marionette lines

What does the study involve?
The Perfectha Derm Lidocaine dosage given depends on the participant and their wrinkle severity (up to 3 ml of products per area and per side of the face can be used). The product will be administered by subcutaneous injection (under the skin). One initial injection will be done on the first visit and a touch-up injection (not mandatory) can be done at the follow-up visit of Month 1. Several follow-up visits will be carried out on day 14, 1 month, 3 months, 6 months and 9 months after the treatment to assess the safety and effectiveness of the injection.

What are the possible benefits and risks of participating?
The expected possible benefits are the aesthetic improvement of nasolabial folds and or marionette lines, and an aesthetic improvement of the face.

Where is the study run from?
Eurofins Dermscan Pharmascan (France)

When is the study starting and how long is it expected to run for?
July 2022 to November 2023

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

Who is the main contact?
Stuart Boothman
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number
2022-A01654-39

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
22E1033

Study information

Scientific Title
Clinical study for the safety and effectiveness of the use of Perfectha® Derm lidocaine in the treatment of medium lines and depressions

Study objectives
The proportion of subjects having an improvement on the Global Aesthetic Improvement scale (GAIS) on the primary treated area 3 months after treatment is statistically superior to 66%.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Approved 03/11/2022, comité de protection des personnes Ile de France I (Hôpital Hôtel Dieu - 1, place du Parvis Notre Dame, 75004, Paris, France; +33 (0)142348052; cppidf1.htd@aphp.fr), ref: CPPIDF1-2022-DI-81 IC-Cas 4.1

Study design
Prospective open-label multi-centre intra-individual trial

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Pharmaceutical testing facility

Study type(s)
Treatment

Participant information sheet
Not available

Health condition(s) or problem(s) studied
Mild to medium lines and depressions (mild to moderate nasolabial folds) and shallow to moderate marionette lines

Interventions
1. 35 subjects minimum for group 1 with nasolabial fold (NLF) treatment
2. 35 subjects minimum for group 2 with marionette lines (ML) treatment
A subject can be included in both groups

The Perfectha Derm Lidocaine dosage given depends on the treated subject and their wrinkle severity (up to 3 ml of products per area and per side of the face can be used). The product will be administered by subcutaneous injection. One initial injection on the D0 visit will be done and a touch-up injection (not mandatory) can be done at the follow-up visit of Month 1. Follow-up will be done until Month 9 after the initial injection. No randomisation process.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Perfectha Derm 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 month (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. Improvement of treated areas is measured using Wrinkle Severity Rating Scale (WSRS) and/or Marionette Lines Grading Scale (MLGS) scale evaluated by an independent live assessor at baseline, M1, M3, M6 and M9
4. Improvement of treated areas is measured using WSRS and/or MLGS scale evaluated by a blinded assessor on photographs at baseline, M1, M3, M6 and M9
5. Subject satisfaction is measured using an internal questionnaire at baseline, M1, M3, M6 and M9
6. Injector satisfaction is measured using an internal questionnaire after injection at D0 and M1
7. Procedural pain is measured 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
27/07/2022

Completion date
08/11/2023

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 a hyaluronic acid filler product
4. Subject presenting mild to medium lines and depressions such as:
4.1. Mild to moderate NLFs (score 2 or 3 on both sides of the face [identical score on both sides required] on the Wrinkle Severity Rating Scale [WSRS]) as assessed live by the independent investigator
and/or
4.2. Shallow to moderate marionette lines (score 1 or 2 on both sides of the face [identical score on both sides required] on the Marionette Lines Grading Scale [MLGS]) as assessed live by the independent investigator
5. The extent(s) of the subject’s nasolabial folds or marionette lines is/are sufficient that it is possible to achieve at least a 1-point improvement on the WSRS or MLGS scale with study intervention based on the judgement of the live independent investigator
6. Subject having given freely and expressly his/her informed consent and data privacy consent
7. Subject affiliated with a health social security system
8. Subject willing to have photographs of the face taken and who are willing to provide approval for the use of their study data and anonymized photographs in published literature
9. Subject willing and able to comply with study follow-up procedures and schedule
10. Females of childbearing potential should use a medically accepted contraceptive regimen since at least 12 weeks prior to study entry and during the study.
11. Subjects willing to commit to having no further facial aesthetic treatments for the duration of the study period, including follow-up:
11.1. For the subjects treated in NLF, no treatment in the mid-face/cheeks and nose area
11.2. For the subjects treated in ML: no treatment on the lips or nose

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
25 Years

Upper age limit
65 Years

Sex
Both

Target number of participants
70

Total final enrolment
70

Key exclusion criteria
1. Pregnant or nursing woman or planning a pregnancy during the study
2. Subject who has 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 the 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. Subject with major dental problems or major dental procedure within 6 weeks before screening visit or planned during the study
7. Subject under epidemiologic surveillance or in quarantine linked to the COVID-19 pandemic
8. 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
9. Subject with a known history of or suffering from autoimmune disease and/or immune deficiency
10. Subject with uncontrolled epilepsy
11. Subject with porphyria
12. Subject with a known history of streptococcal disease (recurrent throat infections, acute rheumatic fever with or without cardiac involvement)
13. Subject suffering from active disease such as inflammation, infection, tumours, inflammatory and/or infectious cutaneous disorders (recurrent herpes, acne, rosacea) on or around the mouth within 6 months of the study entry
14. Subject predisposed to keloids or hypertrophic scarring
15. Subject with known bleeding/clotting disorder or is receiving medication that will likely increase the risk of bleeding during treatment (taking thrombolytics, anticoagulants, aspirin, non-steroidal anti-inflammatory drugs or vitamin C) during 10 days before each injection
16. Subject with a known history of precancerous lesions/skin malignancies on the face
17. Subject with hypersensitivity or with known allergy to hyaluronic acid, lidocaine, amide-type local anaesthetics, avian proteins, feathers and egg or to one of the antiseptic solutions (chlorhexidine)

18. Subject with a known history of severe allergy or anaphylactic shock
19. Subject having received any medication which may interfere, at the interpretation of the investigator, with the study objectives in terms of effectiveness and safety
20. Subject receiving medical treatment that reduces or inhibits liver metabolism (cimetidine, beta-blockers)
21. 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 treated area within the past 6 months
22. Subject having received surgery anywhere on the face within the past 6 months (12 months of washout are required for the cervicofacial lifting and rhinoplasty)
23. Subject having received within the past 12 months any hyaluronic acid filler treatment anywhere in the face
24. Subject having received within the past 24 months any semi-permanent filler (e.g., CaHA, poly-L-lactic acid) anywhere in the face or having received anytime any botulinum toxin or semi-permanent filler on the treated areas
25. Subject having received at any time a fat injection or permanent facial implants (eg, polymethylmethacrylate, silicone, polytetrafluoroethylene) on the face
26. Subjects with subcutaneous retaining structure on the face (meshing, threads, gold strand etc)
27. 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
16/11/2022

Date of final enrolment
19/01/2023

Locations

Countries of recruitment
France

Study participating centre
Eurofins Dermscan Pharmascan
114 Bd. du 11 Novembre 1918
Villeurbanne
France
69100

Sponsor information

Organisation
Sinclair Pharma

Sponsor details

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Sponsor type
Industry

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https://ror.org/00ab7gt92

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
01/10/2024

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	16/05/2024	16/05/2024	No	No