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Clinical study to evaluate the safety and effectiveness of the use of two hyaluronic acid injectable products (Perfectha® Derm Lidocaine and Perfectha® Deep Lidocaine) in the treatment of lips

Submission date 14/11/2022	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 17/11/2022	**Overall study status** Completed	
Last Edited 30/10/2024	**Condition category** Other	

Plain English summary of protocol

Background and study aims
Lip fullness and definition are key facial aesthetic factors associated with attractiveness and youth. The relative attractiveness of the lips is determined by a combination of proportion, definition, and volume. Lips are prone to multiple factors that can dramatically change their shape over time. As humans age, natural substances that provide the skin with structure and volume, such as collagen and hyaluronic acid, decrease. This, along with environmental factors such as exposure to sun damage, smoking, etc, contribute to how lips age, losing volume and forming wrinkles. Procedures on the lips have become increasingly common and popularity has grown due to cultural trends and the association of lip appearance with both youth and beauty. Many patients desire lips filler injections to improve the fullness and definition of this anatomic structure. The aim of this study is to evaluate the effectiveness and safety of two of these products, Perfectha® Derm Lidocaine and Perfectha® Deep Lidocaine, for the treatment of lip volume and for lip contour redefinition.

Who can participate?
Subject aged 18-65 years seeking treatment for lip volume and for lip contour redefinition (if applicable)

What does the study involve?
The study involves an injection of Perfectha® Derm Lidocaine (half of the population) or Perfectha® Deep Lidocaine (the other half of the population). 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 lip area. 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?
Private office of Dr Converset and Dr Baspeyras (France)

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

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

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
22E1021

Study information

Scientific Title

Assessment of the safety and effectiveness of the use of Perfectha® Derm Lidocaine and Perfectha® Deep Lidocaine in the treatment of lips

Study objectives
Perfectha® Derm Lidocaine and Perfectha® Deep Lidocaine induce a global aesthetic improvement of the lip area

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 26/10/2022, Comité de protection des personnes Sud-Ouest et outre mer III (Groupe hospitalier Pellegrin - Bat 1A, Place Amélie Raba Léon, 33076 Bordeaux Cedex, France; +33 (0)5 57 81 76 07; cpp.soom3@u-bordeaux.fr), ref: 22.03137.000120 / 2022-A01589-34

Study design
Prospective open-label multicentre intra-individual study

Primary study design
Interventional

Study type(s)
Other

Health condition(s) or problem(s) studied
For Perfectha® Derm Lidocaine: very thin to thin lip volume and with lip contour somewhat well-defined to poorly defined; for Perfectha® Deep Lidocaine: thin to moderate lip volume

Interventions
34 will be included in group 1 and treated for lip contour definition and lip volume with Perfectha® Derm Lidocaine.
34 will be included in group 2 and treated for lip volume with Perfectha® Deep Lidocaine.
The dosage given depends on the treated subjects and his/her needs (up to 3 ml of products per injection can be used). The product will be delivered by submucosal 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 carried out until Month 9 after the initial injection. There is no randomisation process.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Perfectha® Derm Lidocaine, Perfectha® Deep Lidocaine

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

Key secondary outcome(s))
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. Improvement of treated areas is measured using Rossi and/or Draelos vermillion border evaluated by an assessor on photographs at baseline, M1, M3, M6 and M9
4. Subject's satisfaction is measured using an internal questionnaire at baseline, M1, M3, M6 and M9
5. Injector satisfaction is measured using an internal questionnaire after injection at D0 and M1
6. Procedural pain is measured using a 0 to 10 points pain scale at D0 and M1 after injection
7. Safety is measured using Injection Site Reactions (ISR) rated by a live assessor and by the subjects and by the collection of adverse events after treatment, at M1, M3, M6 and M9

Completion date
30/11/2023

Eligibility

Key inclusion criteria
1. Sex: female or male
2. Age: between 18 and 65 years
3.1. For group 1: subject seeking treatment for lip volume and for lip contour redefinition
3.2. For group 2: subject seeking treatment for lip volume
4.1. For group 1: subject with very thin to thin lip volume (grade 1 to 2 for superior and/or inferior lip on the Rossi scale) and with lip contour somewhat well-defined to poorly defined (grade 2 or 3 on the Draelos vermilion border scale)
4.2. For group 2: subject with thin to moderate lip volume (grade 2 to 3 for superior and/or inferior lip on the Rossi 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 who are 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 with 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 the study
10. Subject willing to commit to having no further facial aesthetic treatments on the nose, lips, perioral lines and marionette lines for the duration of the study period, including follow-up

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

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 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 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 terms 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 a known history of or suffering from autoimmune disease and/or immune deficiency
12. Subject with uncontrolled epilepsy
13. Subject with porphyria
14. Subject with a 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 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, non-steroidal anti-inflammatory drugs or vitamin C) during 10 days before each injection
18. Subject with a known history of precancerous lesions/skin malignancies on/around the 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 a 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 terms 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 lips within the past 6 months
24. Subject having received surgery anywhere on the face within the past 6 months (12 months of washout are required for the cervicofacial lifting)
25. Subject having received within the past 12 months any hyaluronic acid filler treatment on the lips, perioral lines, marionette lines or nose. Injection in the areas listed above, to gain access to other areas of the face, are also non-allowable
26. Subject having received at any time fillers of animal origin, implant containing a substance other than hyaluronic acid, permanent or semi-permanent implants, autologous fat transfer or

threading surgery on the lips, perioral lines, marionette lines or nose
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
19/11/2022

Date of final enrolment
28/02/2023

Locations

Countries of recruitment
France

Study participating centre
Doctor Converset-Viethel office
Palais de Flore
10 Boulevard Jules Favre
Lyon
France
69006

Study participating centre
Doctor Baspeyras office
45 Avenue bel air
Bordeaux
France
33200

Sponsor information

Organisation
Sinclair Pharma

ROR
https://ror.org/00ab7gt92

Funder(s)

Funder type

Industry

Funder Name
Sinclair Pharmaceuticals Limited

Results and Publications

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			30/10/2024	No	No