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Clinical study to evaluate the effectiveness and safety of an implantable suture on the face for the treatment of sagging skin and wrinkles

Submission date
14/12/2021

Recruitment status
No longer recruiting

Registration date
14/01/2022

Overall study status
Completed

Last Edited
16/12/2021

Condition category
Skin and Connective Tissue Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Silhouette Soft® is a resorbable sterile suture that is implanted by a physician on the face and neck for aesthetic purposes. The aim of this study is to find out whether implantation of the suture lifts the skin and improves wrinkles and skin sagging. Silhouette Soft® sutures have been on the European market since 2012.

Who can participate?
People aged 35-50 years with moderate to severe nasolabial folds (wrinkles that form alongside the inner cheeks) and mild to moderate skin laxity (looseness) seeking an improvement of wrinkle severity and skin quality on the mid-face

What does the study involve?
The study involves the implantation of several sutures in the mid-face and chin at the initial visit. The number of sutures is determined by the physician according to the nasolabial fold severity. Several follow-up visitswill be carried out at 7 days, 1 month, 9 months, 12 months and 18 months after implantation to assess the safety and effectiveness of the product.

What are the possible benefits and risks of participating?
The possible benefit is an aesthetic improvement of the face. Like all procedures of this type there is a possibility of adverse events, although not everybody experiences them. These adverse events include infection, minimal acute inflammatory tissue reaction, pain (which may be temporary or persistent in nature), swelling and oedema, transient haematoma (collection of blood) or bruising and transient rippling or dimple formation. Other potential adverse events include ecchymosis (bruising), sensory/motor nerve injury, asymmetry, banding, suture migrations and palpable thread ends/knots. Material sensitivity/allergic reactions may occur.

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

When is the study starting and how long is it expected to run for?
February 2020 to August 2023

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

Who is the main contact?
John Meadows
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
19E2210

Study information

Scientific Title
A prospective, single-center, clinical study to evaluate the efficacy and safety of silhouette soft suture as a treatment of nasolabial folds and jowl laxity

Study objectives
Silhouette Soft® induces an improvement of the nasolabial folds in more than 50% of the treated population.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 29/06/2021, CPP Ile de France XI (Pavillon Jacques Courtois, 2e étage, 20 rue Amargis, 78105 Saint Germain en Laye Cedex; +33 (0)1 39 27 42 58; cppidf11.chips@ght-yvelinesnord.fr), ref: 21041-69309

Primary study design
Interventional

Study design
Prospective interventional single-center clinical study

Study type(s)
Other

Health condition(s) or problem(s) studied
Moderate to severe nasolabial folds severity and mild to moderate skin laxity

Interventions
24 subjects will be included in total and treated with Silhouette Soft® (SMS 22, SMS 23 and SMS 26). The number of sutures to be implanted depends on the naslabial fold severity. Sutures are implanted on the mid-face and chin by a surgeon once at the beginning of the study. The overall duration of the study is 21 months (including screening period and 18 months of follow-up)

Intervention Type
Device

Phase
Phase IV

Drug/device/biological/vaccine name(s)
Silhouette Soft®: Silhouette Soft 8 cones (SMS 22), Silhouette Soft 12 cones (SMS 23 and 26)

Primary outcome(s)
Nasolabial folds severity is measured using the Wrinkles Severity Rating Scale (WSRS) by a live evaluator, 9 months after implantation of the device

Key secondary outcome(s)
1. Nasolabial folds severity is measured using the Wrinkles Severity Rating Scale (WSRS) by a live evaluator 4, 12 and 18 months after implantation of the device
2. Jawline laxity is measured using the Facial Laxity Rating (FLR) scale by a live evaluator 4, 9, 12 and 18 months after implantation of the device
3. Nasolabial folds severity is measured using Wrinkles Severity Rating Scale (WSRS) by an independent evaluator on photographs 4, 9, 12 and 18 months after implantation of the device
4. Jawline laxity is measured using the Facial Laxity Rating (FLR) scale by an independent evaluator on photographs 4, 9, 12 and 18 months after implantation of the device
5. Nasolabial folds depth and volume are measured using Facial Laxity Rating (FLR) scalefringe projection system (Dermatop) 4, 9, 12 and 18 months after implantation of the device
6. Skin quality is measured using Dermascan, Cutometer and Dermatop 4, 9, 12 and 18 months after implantation of the device
7. Skin collagenesis is measured by analysis of biopsies taken at the level of the suture samples implanted under the chin 4, 9, 12 and 18 months after implantation of the device
8. Global aesthetic measurement is measured using the Global Aesthetic Improvement Scale (GAIS) evaluated by the subjets 4, 9, 12 and 18 months after implantation of the device
9. Physician satisfaction is measured using a questionnaire completed after device implantation on D0

10. Subjects satisfaction is measured using a questionnaire 4, 9, 12 and 18 months after implantation of the device
11. Safety is measured using a cutaneous reaction scale rated by a live evaluator and by the subjects and by the collection of adverse events until 18 months after implantation of the device

Completion date
15/08/2023

Eligibility

Key inclusion criteria
1. Healthy subject
2. Sex: male or female
3. Age: between 35 and 50 years
4. Subject with a BMI comprised between 18.5 and 30 kg/m²
5. Subject with no ongoing or planned diet
6. Subject with moderate to severe nasolabial folds as determined by a WSRS score of 3 to 4 in both folds (balanced ratio)
7. Subject with a mild to moderate skin laxity as determined by an FLR score of 3 to 6 on both sides of the face
8. Subject with dense and not too thin skin
9. Subject seeking for an improvement of their wrinkle's severity and skin quality on the mid-face by an aesthetic procedure
10. Subject having given freely and expressly his/her informed consent
11. Subject willing and able to comply with study follow-up procedures and schedule
12. Subject affiliated to a health social security system
13. Females of childbearing potential should use a contraceptive regimen recognized as effective since at least 4 weeks before the beginning of the study and during all the study

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 suspected to be non-compliant according to the investigator's judgment

5. Subject having received 4500 euros indemnities for participation in researches involving human beings in the 12 previous months, including participation in the present study
6. Subject enrolled in another clinical trial or which exclusion period is not over
7. Subject suffering from a serious or progressive disease, which, in the investigator's judgment, puts the subject at undue risk (e.g. diabetes, autoimmune pathology, cardiac pathologies (Coronary heart failure, ventricular rhythm disturbances, severe hypertension, obstructive cardiomyopathy), hyperthyroidism, hepatic deficiency, epilepsy, porphyria)
8. Subject has an acute inflammatory process or infection, or history of chronic or recurrent infection or inflammation with the potential to interfere with the study results or increase the risk of adverse events
9. Subject has a disorder that may impact wound healing such as connective tissue or immunosuppressive disorder
10. Subject has a history of precancerous lesions/skin malignancies
11. Subject with active skin disease within 6 months of study entry
12. Subject with scars, rosacea, herpes, acne, blotches or other pathology in the mid-face, at the investigator appreciation
13. Subject predisposed to keloidosis or hypertrophic scarring
14. Subject with known history of hyper- or hypo-pigmentation in the mid-face
15. Subject has a known history of multiple allergies, allergic/anaphylactic reactions including hypersensitivity to lidocaine, anaesthetics of the amide type, sulfites or the used antiseptic components (chlorhexidine and quaternary ammonium), to the antibiotics of tetracycline family or to lanoline or wool fat
16. Subject has a known bleeding disorder or is receiving medication that will likely increase the risk of bleeding during treatment
17. Subject with extensive skin laxity, thin skin and/or severe malar fat sagging

Date of first enrolment
02/09/2021

Date of final enrolment
15/02/2022

Locations

Countries of recruitment
France

Study participating centre
Eurofins Pharmascan
114 Boulevard du 11 Novembre 1918
Villeurbanne
France
69100

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