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Efficacy and safety of two hyaluronic acid fillers for the treatment of moderate-to-severe nasolabial folds in a Chinese population

Submission date
25/04/2024

Recruitment status
No longer recruiting

Registration date
01/05/2024

Overall study status
Completed

Last Edited
30/04/2024

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
Nasolabial folds (NLFs) are creases in the skin extending from both sides of the nose to the corners of the mouth and are among the early indicators of the facial ageing process. With the ongoing development of biomaterials including hyaluronic acid (HA), minimally invasive injection procedures for the aesthetic correction of NLFs have become the preferred choice in recent years. The widespread use of HA has resulted in the development of various types of commercial HA fillers, such as Cutegel and Restylane. It is well known that HA filler products produce varying effects due to differences in their components and physical properties. Previous studies have established that Restylane is a safe and effective HA dermal filler for the correction of NLFs. However, there is a lack of studies on both the cosmetic results and safety data for Cutegel. Therefore, the aim of this study is to investigate the effectiveness and safety of Cutegel for the correction of moderate-to-severe NLFs compared to the approved Restylane in China.

Who can participate?
People aged 18-65 years with moderate-to-severe NLFs

What does the study involve?
Participants were randomly allocated to either the test group receiving a Cutegel injection or the control group receiving a Restylane injection. Importantly, the individuals administering the gel will not know which brand it is. At the initial treatment, a maximum volume of 1.5 ml was administered per treatment site. If needed at the week 4 followup visit, a touchup treatment could be administered, with a maximum volume of 0.5 ml per treatment site, using the same product as received at the initial treatment in each NLF.

What are the possible benefits and risks of participating?
Participants could benefit from the aesthetic correction of NLFs. However, it's essential to be aware of potential risks, such as swelling, pain, erythema (redness), bleeding, pruritus (itching), and induration (hardening) at the injection site.

Where is the study run from?
The study was conducted at seven sites in China, including Beijing Tsinghua Changgung Hospital (China)

When is the study starting and how long is it expected to run for?
January 2018 to August 2022

Who is funding the study?
Shandong Danhong Pharmaceutical Co. Ltd (China)

Who is the main contact?
Dr Hui Shao, sh.2020@tsinghua.org.cn

Study website
https://www.btch.edu.cn/

Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
MI121-CSR-20220916

Study information

Scientific Title
A 52-week follow-up, multicenter, randomized, double-blinded comparison of efficacy and safety of two hyaluronic acid fillers for the treatment of moderate-to-severe nasolabial folds in a Chinese population

Study objectives
As an approved hyaluronate (HA) filler in Korea, Cutegel provided an alternative treatment option for Chinese subjects with moderate-to-severe nasolabial folds (NLFs).

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 12/06/2018, Beijing Hospital Ethics Committee (No. 1 Dahua Road, Dongdan, Beijing, 100005, China; +86 (0)56118567; zhaohy@163.com), ref: 2018BJYYEC-076-02

Study design
Randomized prospective double-blind multicenter 52-week clinical trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment, Safety, Efficacy

Participant information sheet
Not available in web format

Health condition(s) or problem(s) studied
Moderate-to-severe nasolabial folds in Chinese patients

Interventions
This study was a randomized, prospective, double-blinded, multicenter, 52-week clinical trial conducted in China to evaluate the efficacy and safety of Cutegel in the aesthetic treatment of moderate-to-severe NLFs with Restylane serving as the comparator. Subjects were randomly allocated to the test or control group in a 1:1 ratio. Allocation concealment was ensured through the use of a random number table.

1. Cutegel® MAX (20 mg/1.1 ml), a transparent gel that is based on stabilized hyaluronic acid of non-animal origin, administered with a 23-gauge sterile needle
2. Restylane® (20 mg/1.0 ml, Q-Med, AB company), a popular dermal filler that consists of nonanimal, stabilized hyaluronic acid, administered with a sterilized 30-gauge needle.

Study visits were scheduled as follows: screening, baseline (initial treatment), Week 4 (optional touch-up), Week 12, Week 24, and Week 52 after the last treatment. If an optional touch-up treatment was performed to correct any observed unevenness in both NLFs, a second 4-week follow-up visit was arranged.

Intervention Type
Drug

Pharmaceutical study type(s)
Not Applicable

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Cutegel® MAX, Restylane®

Primary outcome measure
The response rate of NLF correction at week 24 after the last injection treatment. The response rate was characterized as the percentage of subjects exhibiting an improvement of at least one-point based on the Wrinkle Severity Rating Scale (WSRS) assessed by a blinded evaluator.

Secondary outcome measures
1. Wrinkle severity evaluated on the WSRS by a blinded evaluator at Week 4, 12, and 52
2. Aesthetic improvement evaluated on the Global Aesthetic Improvement Scale (GAIS) by both subjects and a blinded evaluator at Week 4, 12, 24 and 52

Overall study start date
01/01/2018

Completion date
17/08/2022

Eligibility

Key inclusion criteria
1. Male and female subjects aged 18-65 years
2. Nasolabial crease WSRS grade 3-4 and wish to correct the subject
3. Subjects with nasolabial crease of the same WSRS grade on both sides
4. Participants who agreed not to use other cosmetic treatments related to the study
5. Understand and comply with the requirements of the trial, can complete the whole follow-up process of the subjects
6. Volunteer to participate in the study and sign the informed consent form

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Both

Target number of participants
340

Total final enrolment
339

Key exclusion criteria
1. Pregnant or lactating women
2. Women of childbearing age who did not agree to use medically approved contraceptive methods (e.g. oral contraceptives, condom, intrauterine device) during the trial
3. The abnormal laboratory results were judged by the researcher as having clinical significance
4. Subjects with scarring or skin diseases in the trial treatment area that may affect the judgment of treatment efficacy, or with active inflammation and/or unhealed wounds
5. Subjects with active inflammation and skin infection in the experimental treatment area
6. Subjects who had received silicone or other permanent dermal fillers in the treatment area
7. Subjects who had undergone facial lifting surgery or catgut-embedding surgery within 1 year of the screening period
8. The subjects were treated with sodium hyaluronate or other semi-permanent dermal fillers within 1 year before the screening period
9. Within 6 months before the screening period, the subjects underwent other treatments such as botulinum toxin injection, radiofrequency ablation, focused ultrasound, laser peels, grinding, chemical peeling, etc
10. Participants who had used anticoagulant, antiplatelet, or thrombolytic therapy (e.g. , Warfarin, aspirin) within 14 days before study treatment or planned to use it within 3 days after study treatment
11. Had a history of multiple severe allergies, a history of inherited allergies, a history of allergy to hyaluronic acid products or streptococcal protein, and planned desensitization treatment during the study period
12. The subjects had a history of serious diseases of their vital organs or autoimmune diseases
13. The subjects had a history of hypertrophic scar or scar formation
14. Subjects who had participated in other clinical trials within 30 days before the screening period
15. The study participants were considered unsuitable for the study

Date of first enrolment
02/07/2019

Date of final enrolment
01/09/2021

Locations

Countries of recruitment
China

Study participating centre
Beijing Hospital
1 Dahua Road
Dongdan
Beijing
China
100005

Study participating centre
Shanghai Tongji Hospital
389 Xincun Road
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China
200065

Study participating centre
Beijing Tsinghua Changgeng Hospital
168 Litang Road
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Study participating centre
Nanjing Drum Tower Hospital
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Study participating centre
National Sun Yat-sen University Sun Yat-sen Memorial Hospital
107 Yanjiangxi Road
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528403

Study participating centre
Nanyang Nanshi Hospital
Nanyang
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Sponsor information

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Beijing Tsinghua Chang Gung Hospital

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Sponsor type
Hospital/treatment centre

Website
https://www.tsinghua.edu.cn/publish/chgen/

ROR
https://ror.org/050nfgr37

Funder(s)

Funder type
Industry

Funder Name
Shandong Danhong Pharmaceutical Co. Ltd.

Results and Publications

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

Intention to publish date
31/12/2024

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a non-publicly available repository: http://www.medresman.org.cn/login.aspx

IPD sharing plan summary
Stored in non-publicly available repository