

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	☐ Prospectively registered
		☐ Protocol
Registration date 01/05/2024	Overall study status Completed	☐ Statistical analysis plan
		☐ Results
Last Edited 30/04/2024	Condition category Skin and Connective Tissue Diseases	☐ 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

Contact information

Type(s)

Public, Scientific, Principal investigator

Contact name

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Additional identifiers

Protocol serial number

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

Primary study design

Interventional

Study design

Randomized prospective double-blind multicenter 52-week clinical trial

Study type(s)

Treatment, Safety, Efficacy

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

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Cutegel® MAX, Restylane®

Primary outcome(s)

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.

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Upper age limit

65 Years

Sex

All

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

Shanghai

China

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Study participating centre

Beijing Tsinghua Changgeng Hospital

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Study participating centre**National Sun Yat-sen University Sun Yat-sen Memorial Hospital**

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Study participating centre**Nanyang Nanshi Hospital**

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Sponsor information

Organisation

Beijing Tsinghua Chang Gung Hospital

ROR

<https://ror.org/050nfgr37>

Funder(s)

Funder type

Industry

Funder Name

Shandong Danhong Pharmaceutical Co. Ltd.

Results and Publications

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Study website	Study website	11/11/2025	11/11/2025	No	Yes