

Safety and effect of cross-linked hyaluronic acid injectable dermal fillers

Submission date 05/06/2026	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input checked="" type="checkbox"/> Protocol
Registration date 08/06/2026	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 05/06/2026	Condition category Skin and Connective Tissue Diseases	<input type="checkbox"/> Individual participant data
		<input checked="" type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Nasolabial fold wrinkles (natural creases extending from the nose to the corners of the mouth) are a common sign of facial ageing, which can affect facial aesthetics. Dermal filler injection is a minimally invasive and widely used method to improve facial wrinkles. This clinical study aims to verify the filling effect and human skin safety of injectable cross-linked hyaluronic acid dermal fillers manufactured by Dr Korman Laboratories Ltd in the correction of moderate to severe nasolabial fold wrinkles.

Who can participate?

Men and women aged 18 to 65 years with moderate to severe nasolabial fold wrinkles

What does the study involve?

Participants will be randomly assigned to either the experimental group or the control group. Participants in the experimental group will receive an injection of cross-linked sodium hyaluronate gel for injection manufactured by Dr Korman Laboratories Ltd into the middle to deep layer of facial dermal tissue. Participants in the control group will receive an injection of modified sodium hyaluronate gel for injection produced by Q-Med AB into the middle layer of facial dermal tissue. Researchers will evaluate the wrinkle improvement effect at different follow-up timepoints after treatment and monitor the safety of the study product throughout the study period.

What are the possible benefits and risks of participating?

Participants with moderate to severe nasolabial fold wrinkles may obtain effective improvement of facial wrinkles and better facial aesthetic status after receiving dermal filler treatment. Participants will receive free study-related treatment and professional clinical follow-up examinations during the study period.

Similar to routine hyaluronic acid filler injection, participants may experience mild and temporary adverse reactions, including redness, swelling, bruising, pain or itching at the injection site. These discomforts usually relieve gradually within a short time. Severe adverse reactions are rare.

Where is the study run from?

The study is conducted at multiple clinical sites in China, including Zhejiang Provincial People's Hospital, Zhejiang Hospital, Shulan (Hangzhou) Hospital, Sir Run Run Shaw Hospital, Zhejiang University School of Medicine, and Zhejiang Provincial Tongde Hospital.

When is the study starting and how long is it expected to run for?

September 2022 to August 2025

Who is funding the study?

Shanghai Lumed Trading Co., Ltd (China)

Who is the main contact?

Wen Gu, colin.gu@i-lumed.com

Contact information

Type(s)

Principal investigator, Scientific, Public

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Clinical trial filing number

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Study information

Scientific Title

A multicenter, double-blind, randomized, parallel-controlled, non-inferiority clinical trial to evaluate the efficacy and safety of injectable cross-linked hyaluronic acid dermal fillers

Acronym

CHADF

Study objectives

To verify the filling effect and human skin safety of cross-linked hyaluronic acid dermal fillers for injection manufactured by Dr Korman Laboratories Ltd in correcting moderate to severe nasolabial fold wrinkles.

Ethics approval required

Ethics approval required

Ethics approval(s)

approved 22/09/2021, Ethics Committee of Zhejiang Provincial People's Hospital (No. 158 Shantang Road, Hangzhou, 310014, China; +86 (0)571 8589 3643; zryllwyh@163.com), ref: () 2021QX022

Primary study design

Interventional

Allocation

Randomized controlled trial

Masking

Blinded (masking used)

Control

Active

Assignment

Parallel

Purpose

Treatment

Study type(s)

Health condition(s) or problem(s) studied

Moderate to severe nasolabial fold wrinkles

Interventions

This is a two-arm interventional study enrolling subjects with moderate to severe nasolabial fold wrinkles. Eligible participants are randomly allocated into either the experimental arm or the control arm. Random assignment was completed by computer randomization system. The random sequence was generated by dedicated statistical software, and the system automatically distributes enrolled participants to the study group or control group to balance baseline confounding factors across groups.

Experimental intervention:

Subjects receive an intradermal injection of cross-linked sodium hyaluronate gel for injection (26 mg/ml) manufactured by Dr Korman Laboratories Ltd; the product is administered into the middle to deep layer of facial dermis for the correction of moderate to severe nasolabial fold wrinkles, with injection dose determined per trial protocol.

Control intervention:

Subjects receive an intradermal injection of modified sodium hyaluronate gel for injection manufactured by Q-Med AB; the product is injected into the middle layer of facial dermal tissue to fill and correct moderate to severe nasolabial fold wrinkles, with the injection dose specified in the study protocol.

Intervention Type

Device

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Cross linked hyaluronic acid injectable dermal fillers

Primary outcome(s)

1. Overall clinical effective rate for nasolabial fold wrinkles measured using the Wrinkle Severity Rating Scale (WSRS) at 6 months after treatment administration

Key secondary outcome(s)

1. Clinical effective rate of nasolabial fold wrinkles measured using the Wrinkle Severity Rating Scale (WSRS) at 1 month, 3 months and 12 months after treatment completion

2. Global facial wrinkle improvement measured using the Global Aesthetic Improvement Scale (GAIS) at 1 month, 3 months, 6 months and 12 months after treatment completion

Completion date

07/08/2025

Eligibility

Key inclusion criteria

1. Male or female Chinese subjects aged 18 to 65 years old (inclusive)
2. Assessed by the investigator to have obviously visible and approximately symmetrical bilateral wrinkles, with consistent bilateral scores of 3 or 4 points on the 5-point Wrinkle Severity Rating Scale (WSRS), and having reasonable expectations for the wrinkle correction effect described in this study protocol
3. Voluntarily participate in this clinical trial and sign the informed consent form

Healthy volunteers allowed

No

Age group

Mixed

Lower age limit

18 years

Upper age limit

65 years

Sex

All

Total final enrolment

354

Key exclusion criteria

1. Abnormal laboratory test results judged clinically significant by the investigator and unsuitable for participation in the clinical study
2. Females of childbearing age who are pregnant, breastfeeding, planning to become pregnant, or not using reliable contraceptive measures, and are unwilling to adopt medically recognized contraceptive methods such as oral contraceptives, condoms and intrauterine devices during the trial period
3. The 5-point Wrinkle Severity Rating Scale score of unilateral or bilateral wrinkles is 1, 2 or 5
4. Obvious acne scars, active inflammation, infection, malignant lesions or precancerous lesions, or unhealed wounds in the injection site
5. Received facial plastic surgery, tissue transplantation, injection of silicone, fat grafting, or injection of other permanent or semi-permanent dermal fillers in the midface within 12 months prior to treatment
6. Received cosmetic botulinum toxin injection, laser resurfacing, photorejuvenation, intense pulsed light, radiofrequency therapy, dermabrasion, chemical peeling or other ablative and non-ablative procedures in the midface within 6 months prior to treatment
7. Used any oral or topical anti-wrinkle products at the treatment area within 90 days prior to treatment
8. Undergoing anticoagulant therapy such as warfarin, or having taken non-steroidal anti-inflammatory drugs including aspirin and ibuprofen, or other substances known to prolong coagulation time such as garlic and ginkgo-containing herbal supplements within 10 days before treatment. Note: Injection may be postponed if necessary to meet the 10-day washout period requirement
9. Participated in any other clinical trial within 3 months prior to treatment
10. Plan to receive any facial plastic surgery or cosmetic treatments such as thread lifting, thermolifting and midface tightening during the study period
11. History of severe allergic reactions, multiple allergies, hereditary allergy, allergy to hyaluronic acid products, or planned desensitization therapy during the study
12. Any other conditions deemed inappropriate for participation in this clinical study by the investigator

Date of first enrolment

27/09/2022

Date of final enrolment

09/07/2024

Locations

Countries of recruitment

China

Sponsor information

Organisation

Shanghai Lumed Trading Co., Ltd

Funder(s)

Funder type

Funder Name

Shanghai Lumed Trading Co., Ltd.

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other files			05/06/2026	No	No
Protocol file			05/06/2026	No	No