

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Evaluating the safety and effectiveness of injectable gel with the W&O XtralIII brand, for correcting nasolabial folds, before and after single clinical trial

Protocol summary

Study aim

Evaluating the safety and effectiveness of injectable gel with the W&O XtralIII brand, for correcting nasolabial folds, before and after single clinical trial

Design

Single group, phase 2, before -after clinical study. sample size is 30. The study is not randomized.

Settings and conduct

The study will be conducted in Center for research and training in skin diseases and leprosy, Tehran University of Medical Sciences. Before intervention face photography will be taken from participants using digital camera and Visioface camera for determination the severity of nasolabial folds, according to Allergan scale. Skin ultrasound also will perform on nasolabial folds. One intradermal injection with W&O XtralIII will be performed on each nasolabial fold. The assessment will be repeated right after intervention and 2, 12 and 24 weeks later. Subjects' satisfaction and adverse effect will be recorded in each follow up visit.

Participants/Inclusion and exclusion criteria

18 -65 years old men and women, with moderate to severe nasolabial folds, without any cosmetic facial procedures during last 3 months, with no allergy to gram positive bacteria protein, gel ingredients and not auto immune or immune deficiency diseases. No pregnant and lactating

Intervention groups

Intervention group: One injection with 1-2 cc W&O XtralIII injectable gel in each nasolabial fold.

Main outcome variables

Severity of nasolabial folds according to Allergan grading

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190210042676N30**

Registration date: **2023-10-08, 1402/07/16**

Registration timing: **registered_while_recruiting**

Last update: **2023-10-08, 1402/07/16**

Update count: **0**

Registration date

2023-10-08, 1402/07/16

Registrant information

Name

Aniseh Samadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8897 2220

Email address

a_samadi@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-10-07, 1402/07/15

Expected recruitment end date

2024-01-05, 1402/10/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the safety and effectiveness of injectable gel with the W&O XtralIII brand, for correcting nasolabial

folds, before and after single clinical trial

Public title
Evaluating the safety and effectiveness of injectable gel with the W&O XtralIII brand

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
18 -65 years old men and women Moderate to severe nasolabial folds based on Allergan criteria. The opportunity to accompany the visit programs and study process. Signing the informed consent form and agree to a 6-month follow-up.
Exclusion criteria:
Previous hyaluronic acid (HA)-based dermal filler treatment(s) injected within the last 12 months prior to enrollment. Cosmetic facial procedures (chemical peel, laser, radio frequency, dermabrasion, ablative or non-ablative procedures), Botox) in the lower 2/3 of the face, within 3 months prior to study entry Planning to undergo any of these procedures at any time during the study.

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of The Institute of Pharmaceutical Sciences of Tehran University of Medical Science

Street address

Unit 1-219, 2nd floor, The Institute of Pharmaceutical Sciences, Faculty of Pharmacy, 16 Azar Avenue

City

Tehran

Province

Tehran
Postal code
1417613151
Approval date
2023-10-02, 1402/07/10
Ethics committee reference number
IR.TUMS.TIPS.REC.1402.084

Health conditions studied

1

Description of health condition studied

Skin aging

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Severity of nasolabial folds

Timepoint

Before intervention and right after intervention and 2, 12 and 24 weeks later

Method of measurement

5 scale Allergan photo numeric grading

Secondary outcomes

1

Description

Depth, area and volume of nasolabial fold

Timepoint

Before intervention and right after intervention and 2, 12 and 24 weeks later

Method of measurement

Visioface camera

2

Description

Thickness and density of dermis

Timepoint

Before intervention and right after intervention and 2, 12 and 24 weeks later

Method of measurement

Skin ultrasound

Intervention groups

1

Description

Intervention group: One injection with 1-2 cc W&O XtralIII injectable gel in each nasolabial fold. W&O XtralIII is a sterile physiological solution, without fever microbial agent. The active ingredient of this product is stabilized sodium hyaluronic acid with non-animal origin.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Center for research and training in skin diseases and leprosy, Tehran University of Medical Sciences

Full name of responsible person

Aniseh Samadi

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No. 415, Shahid Naderi (Soheil) Street, Taleqani Avenue

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1416613675

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dermalab@tums.ac.ir

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Ara Teb Gostar Soroush Company

Full name of responsible person

Mehdi Talebi Ghahroodi

Street address

Unit 3, No. 15, North Mirza Shirazi St., Motahari St.

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Ara Teb Gostar Soroush Company

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Persons

Person responsible for general inquiries**Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Aniseh Samadi

Position

Manger of clinical study unit

Latest degree

Ph.D.

Other areas of specialty/work

Dermatology

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Mansour Nassiri Kashani

Position

Professor of dermatology

Latest degree

Specialist

Other areas of specialty/work

Dermatology

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Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Maryam Ahmadi

Position

Research Expert

Latest degree

Master

Other areas of specialty/work

Dermatology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable