

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

08 Jul 2026

### Evaluation of the effectiveness of wheat callus extract in rejuvenation and reduction of skin wrinkles with clinical evaluation in volunteers

#### Protocol summary

##### Study aim

Comparison of the effect of wheat callus extract in nanoliposomal form with nanoliposomes without drug (as a control) in reducing skin wrinkles and skin rejuvenation in female volunteers

##### Design

The clinical trial has the same control and intervention group, meaning that all people will receive both control and intervention equally, with the difference that they will receive the drug-containing formulation on the right and the drug-free formulation on the left side of the face under equal conditions. This trial is non-blinded and not randomised, phase 2, 3 and parallel study will be performed on 24 women.

##### Settings and conduct

The medicine is prepared monthly in the laboratory and the volunteers will take the medicine and the placebo which is in the form of gel at home, once daily, topically around the eyes and photographing the wrinkles around the eyes of the volunteers in the beauty clinic under the supervision of a dermatologist. Depth of the wrinkles will be compared before and after taking the medicine and placebo. This study, is not blinded and all volunteers will receive both medication and placebo under the same conditions.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Women with wrinkles in parts of the face (around the eyes), age group 30 to 55 years

Exclusion criteria: History of previous allergies to cosmetics, concomitant use of anti-wrinkle products in the study areas, pregnancy and lactation, history of cardiovascular disease and diabetes, and hypothyroidism or hyperthyroidism.

##### Intervention groups

All volunteers will use the drug around the right eye and the placebo as a control around the left eye, and the effects of the drug and placebo will be compared.

##### Main outcome variables

Skin wrinkles and rejuvenate the skin

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20211206053302N1**

Registration date: **2022-01-17, 1400/10/27**

Registration timing: **prospective**

Last update: **2022-01-17, 1400/10/27**

Update count: **0**

##### Registration date

2022-01-17, 1400/10/27

##### Registrant information

##### Name

Ehsan Adhami

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 44 3365 7497

##### Email address

adhamiehsan@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-01-30, 1400/11/10

##### Expected recruitment end date

2022-02-19, 1400/11/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluation of the effectiveness of wheat callus extract in rejuvenation and reduction of skin wrinkles with clinical evaluation in volunteers

**Public title**

Evaluation of the effect of wheat on skin rejuvenation in women

**Purpose**

Supportive

**Inclusion/Exclusion criteria****Inclusion criteria:**

Women with facial wrinkles in the desired areas age of 30 to 55 years

**Exclusion criteria:**

History of previous allergies to cosmetics Estrogen therapy Simultaneous use of anti-wrinkle products in the desired area Pregnancy and lactation History of cardiovascular disease, diabetes, hypothyroidism or hyperthyroidism

**Age**

From **30 years** old to **55 years** old

**Gender**

Female

**Phase**

2-3

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **48**

More than 1 sample in each individual

Number of samples in each individual: **24**

Each volunteer will receive both medication (on one side of the face) and placebo (on the other side of the face).

**Randomization (investigator's opinion)**

N/A

**Randomization description****Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Used

**Assignment**

Parallel

**Other design features**

In this study, all 24 volunteers will use the drug on the right side of the face around the right eye and the placebo on the other side of the face symmetrically, and the effect of the drug and the placebo on reducing wrinkles around the eyes will be compared.

**Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Tabriz University of Medical Sciences

**Street address**

Medical Education Research and Development Complex (formerly Pashmineh), Pharmaceutical Nanotechnology Research Center., Opposite of Shahid Madani Hospital., University St.

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

5165665811

**Approval date**

2021-11-15, 1400/08/24

**Ethics committee reference number**

IR.TBZMED.REC.1400.740

**Health conditions studied****1****Description of health condition studied**

Wrinkles - Skin aging

**ICD-10 code**

R23.8

**ICD-10 code description**

Other skin changes

**Primary outcomes****1****Description**

Comparison of the effect of wheat extract on skin rejuvenation and reduction of depth, size and number of facial wrinkles

**Timepoint**

At the beginning of the study and 3 and 6 months after the start of the trial

**Method of measurement**

Facial photos and scoring by a dermatologist

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Intervention group: Evaluation of the effect of wheat callus extract containing polyphenols, phenolic acid, flavonoids, triterpenes, carotenoids and peptides, in the form of nanoliposomal gel formulation with a concentration of 0.2% for daily topical use (50 mg of Pure active ingredient) once daily for 6 months on the right side of the face (around the right eye) on 24 female volunteers. All stages of preparation of this drug (including culture and preparation of callus and extraction and preparation of nanoliposome formulation and gel form) will be performed by the researcher and no company or organization will have a role in its

preparation.

**Category**

Treatment - Other

**2****Description**

Control group: Evaluation of the effect of drug-free nanoliposomes in gel formulation, once daily topically as a placebo for 6 months on the left side of the face (around the left eye) on 24 female volunteers. All stages of preparation of this drug (including culture and preparation of callus and extraction and preparation of nanoliposome formulation and gel form) will be performed by the researcher and no company or organization will have a role in its preparation.

**Category**

Placebo

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

Research and Technology Center of Tabriz University of Medical Sciences

**Full name of responsible person**

Dr.Hamed Hamishehkar

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

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**Full name of responsible person**

Dr.Hamed Hamishehkar

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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**

Tabriz University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

Public

**Domestic or foreign origin**

Domestic

**Category of foreign source of funding**

*empty*

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

Academic

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

Tabriz University of Medical Sciences

**Full name of responsible person**

Ehsan Adhami

**Position**

pharmacy student

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Medical Pharmacy

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

Tabriz University of Medical Sciences

**Full name of responsible person**

Dr.Hamed Hamishekar

**Position**

Assistant professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Medical Pharmacy

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Ehsan Adhami

**Position**

pharmacy student

**Latest degree**

Medical doctor

**Other areas of specialty/work**

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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**

Yes - There is 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**

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

**Data Dictionary**

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

**Title and more details about the data/document**

-

**When the data will become available and for how long**

-

**To whom data/document is available**

-

**Under which criteria data/document could be used**

-

**From where data/document is obtainable**

-

**What processes are involved for a request to access data/document**

-

**Comments**