

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of the effect of Glycyrrhiza glabra extract in the form of D-Reglis herbal pills on amount of human Saliva: A Crossover randomized clinical trial study

Protocol summary

Study aim

Evaluation of the effect of Glycyrrhiza glabra extract in the form of D-Reglis herbal pills on amount of human Saliva

Design

Randomized clinical trial by block randomization with cross-over groups, phase 3. Double-Blind side. The sample size is 20.

Settings and conduct

This research was a cross-over , randomized and double blind study. The population of the study included healthy individuals aged 18 to 35 years old, including individuals who refer to the dental clinic of North Khorasan University of Medical Sciences and students of this college randomly entered the study as the two experimental and control groups. 2 capsules containing extract of licorice (D-Reglis tablet 380mg) or placebo (starch) were administered orally with 200 mL water. Saliva samples were then collected according to a spitting method at scheduled times. After a 2-week wash-out period, in the second phase, the switch between two groups was performed and the saliva was collected as in the first phase.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Healthy volunteers who have no history of dry mouth, No subject received any medication during 1 month before the study, Signature of the informed consent form
Non-inclusion criteria: subjects who suffer from dry mouth and take medication , Sensitivity to licorice ,Pregnancy, Use cigarettes.

Intervention groups

Give the D-reglis tablet to the intervention group
Give starch tablet to the control group

Main outcome variables

Weight of saliva

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190422043344N1**

Registration date: **2019-06-17, 1398/03/27**

Registration timing: **retrospective**

Last update: **2019-06-17, 1398/03/27**

Update count: **0**

Registration date

2019-06-17, 1398/03/27

Registrant information

Name

Mehdi mohammad sadeghian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 58 3226 1272

Email address

m.sadeghian@nkums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-03-05, 1397/12/14

Expected recruitment end date

2019-03-19, 1397/12/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of Glycyrrhiza glabra extract in the form of D-Reglis herbal pills on amount of human Saliva: A Crossover randomized clinical trial study

Public title

" Effect of Glycyrrhiza glabra extract on salivary volume"

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Healthy volunteers who have no history of dry mouth aged 18-35 years Signature of informed consent form

Exclusion criteria:

1- Pregnancy 2. Those who suffer from dry mouth and take medication 3. Sensitivity to licorice 4- Use of cigarettes 5- Drug use in the previous month before the study

Age

From **18 years** old to **35 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **20**

More than 1 sample in each individual

Number of samples in each individual: **2**

Every person participating in the study at the beginning of the study drug and take placebo two weeks later

Randomization (investigator's opinion)

Randomized

Randomization description

The subjects were divided into two groups A and B according to a randomized double blind block design.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this double-blind study, participants, researchers are unaware of prescription drugs.

Placebo

Used

Assignment

Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

National committee of North khorasan University of medical sciences

Street address

Shahriar Ave., North khorasan University of Medical Sciences

City

Bojnourd

Province

North Khorasan

Postal code

9417694735

Approval date

2019-03-05, 1397/12/14

Ethics committee reference number

IR.NKUMS.REC.1397.099

Health conditions studied

1

Description of health condition studied

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

The weight of saliva secreted from all salivary glands in the mouth

Timepoint

Measurement of saliva volume at the beginning of the study and at 20, 40, 60, 90, 120, and 180 minutes after the administration of the D-REGLIS tablet and placebo

Method of measurement

digital Balance

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: A single dose of 380 milligrams of licorice extract produced by Iran Daruk Co., with 200 cc was prescribed. To prevent the bias between the drug and the placebo, they are placed in the same capsules.

Category

Treatment - Drugs

2

Description

Control group: Placebo (starch), in capsules of the same size and shape as capsules of the drug, and with 200 cc of water was prescribed.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

North Khorasan University of Medical Sciences

Full name of responsible person

Mehdi Mohammad Sadeghian

Street address

Shahriar Ave.; North Khorasan University of Medical Sciences

City

Bojnourd

Province

North Khorasan

Postal code

74877-94149

Phone

+98 58 3229 6764

Email

dr.mm.sadeghian@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bojnourd University of Medical Sciences

Full name of responsible person

Seyed Kaveh Hojjat

Street address

North Khorasan University of Medical Sciences,
Shahriar st, Bojnord

City

Bojnourd

Province

North Khorasan

Postal code

9417694735

Phone

+98 58 3224 6144

Email

dr.mm.sadeghian@gmail.com

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

Yes

Title of funding source

Bojnourd 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

Bojnourd University of Medical Sciences

Full name of responsible person

Mehdi Mohammad Sadeghian

Position

student

Latest degree

A Level or less

Other areas of specialty/work

Dentistry

Street address

Shahriar St., North Khorasan University of Medical Sciences

City

Bojnourd

Province

North Khorasan

Postal code

9417694735

Phone

+98 58 3226 1272

Email

dr.mm.sadeghian@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Bojnourd University of Medical Sciences

Full name of responsible person

Mehdi Mohammad Sadeghian

Position

student

Latest degree

A Level or less

Other areas of specialty/work

Dentistry

Street address

Shahriar St., North Khorasan University of Medical Sciences

City

Bojnourd

Province

North Khorasan

Postal code

9417694735

Phone

+98 58 3624 5629

Email

dr.mm.sadeghian@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Bojnourd University of Medical Sciences

Full name of responsible person

Mehdi Mohammad Sadeghian

Position

student

Latest degree

A Level or less

Other areas of specialty/work

Dentistry

Street address

Shahriar st., North Khorasan University of Medical Sciences

City

Bojnourd

Province

North Khorasan

Postal code

9417694735

Phone

+98 58 3624 5629

Email

dr.mm.sadeghian@gmail.com

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is 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

Yes - There is a plan to make this available

Analytic Code

Yes - There is 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

Information about the main consequence, have the ability to share, after unidentifiable people.

When the data will become available and for how long

Start the access period 6 months after printing the results

To whom data/document is available

Researchers working in academic & scientific institutions

Under which criteria data/document could be used

The use of data in order to complete scientific information and research is permissible and sending a request for access to data has not a specific condition.

From where data/document is obtainable

1. North Khorasan University of Medical Sciences, dental College 2. s.etemadzade@gmail.com

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

After sending the email, it will be answered for a few days

Comments