Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 commitee 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

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Shahriar Ave.; North Khorasan University of Medical Sciences

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Bojnourd University of Medical Sciences

Full name of responsible person
Seyed Kaveh Hojjat

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North Khorasan University of Medical Sciences, Shahriar st, Bojnord

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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
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

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Person responsible for updating data

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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