

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Comparison Of Saliva PH Before And After Consumption Of Licorice Product, A Controlled Clinical Trial

Protocol summary

Study aim

Comparison of salivary ph before and after consumption of licorice products

Design

Clinical trial has intervention and control groups, with cross-over design: The use of licorice product in the intervention group and the use of starch as placebo in control group. Then the place of two groups will be changed after two weeks. Permuted Block Randomization method, The sample size in each group is 14 people, includes the phase 3 of clinical trials, double-blind.

Settings and conduct

The field of the study is interventional. It is done in North Khorasan University of medical sciences. All the samples eat the same breakfast. Saliva sampling is done after taking the drug and the placebo in several stages. Blinding of participants is done through the use of the capsules with the same shape and size. Blinding of researcher is done through giving medication and placebo to the samples by a person other than the researcher.

Participants/Inclusion and exclusion criteria

Entry criteria: 1. Informed consent 2-Age between 20 to 40 years 3-Weight between 56 to 80 kg 4-Not taking the drug one month before the sampling Exit criteria: 1. Allergy to licorice 2-Pregnancy 3. Developing systemic disease 4- History of dry mouth 5- Addiction to cigarettes

Intervention groups

The use of licorice product in the intervention group and the use of starch as placebo in control group. Then the place of two groups will be changed after two weeks.

Main outcome variables

PH of saliva

General information

Reason for update

Acronym

CT

IRCT registration information

IRCT registration number: **IRCT20190314043054N1**
Registration date: **2019-06-12, 1398/03/22**
Registration timing: **retrospective**

Last update: **2019-06-12, 1398/03/22**

Update count: **0**

Registration date

2019-06-12, 1398/03/22

Registrant information

Name

Mohsen Vosough

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 58 3635 7638

Email address

m.vosough@nkums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-01-30, 1397/11/10

Expected recruitment end date

2019-02-14, 1397/11/25

Actual recruitment start date

2019-03-13, 1397/12/22

Actual recruitment end date

2019-03-15, 1397/12/24

Trial completion date

2019-04-14, 1398/01/25

Scientific title

Comparison Of Saliva PH Before And After Consumption Of Licorice Product, A Controlled Clinical Trial

Public title

Comparison Of Saliva PH Before And After Consumption Of Licorice Product, A Controlled Clinical Trial

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

1. Informed consent 2-age between 20 to 40 years 3-Weight between 56 to 80 kg 4-Not taking the drug one month before the sampling

Exclusion criteria:

1-allergy to licorice 2-pregnancy 3-Developing systemic disease 4- addiction to cigarettes 5- History of dry mouth

Age

From **20 years** old to **40 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **28**

More than 1 sample in each individual

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

Each sample receives licorice once and receives placebo once and each time the PH of saliva is measured.

Actual sample size reached: **28**

More than 1 sample in each individual

Actual sample size in each individual: **2**

Each sample receives licorice once and receives placebo once and each time the PH of saliva is measured.

Randomization (investigator's opinion)

Randomized

Randomization description

Permuted Block Randomization method in which the number of samples is equal in each group. In every block, half of the individuals are intervention and the other half of are control ones.

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants: the capsules with identical shape and size are used for drug and placebo. Researcher: medication and placebo are given to the samples by a person other than the researcher.

Placebo

Used

Assignment

Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of North Khorasan University of Medical Sciences

Street address

North Khorasan University of Medical Sciences, Dolat Blvd, Bojnurd, Iran

City

Bojourn

Province

North Khorasan

Postal code

7487794149

Approval date

2019-01-15, 1397/10/25

Ethics committee reference number

IR.NKUMS.REC.1397.090

Health conditions studied

1

Description of health condition studied

Changes in salivary PH-Licorice

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

PH of Saliva

Timepoint

Before the intervention/20,40,60,90,120,180 minutes after the intervention

Method of measurement

PH Meter device-INOLAB 720-made in Germany

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Tablet D-REGLIS, production of Iran DAROUK Company with drug registration number of 1228104305-These pills contain 380 mg of dried and standardized extracts of licorice root. 2 tablets are used in single dose form.

Category

Treatment - Drugs

2

Description

Control group: Tablets containing 50 mg of starch.

production of medicinal plants Institute of Jihad
Daneshgahi. 2 tablets are used in single dose form.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Faculty of Dentistry, North Khorasan University of
Medical Sciences

Full name of responsible person

Mohsen Vosough

Street address

Shahriar Street, Bojnurd, North Khorasan

City

Bojnourd

Province

North Khorasan

Postal code

7487794149

Phone

+98 58 3224 6144

Email

javad.snm68@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

Shahid Mohaghr Alley, Bojnurd, North Khorasan

City

Bojnourd

Province

North Khorasan

Postal code

7487794149

Phone

+98 58 3229 7182

Email

INFO@NKUMS.AC.IR

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

Mohsen Vosough

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Dentistry

Street address

Chalo village - Shirvan - North Khorasan

City

shirvan

Province

North Khorasan

Postal code

9465139375

Phone

+98 58 3635 7638

Email

javad.snm68@gmail.com

**Person responsible for scientific
inquiries**

Contact

Name of organization / entity

Bojnourd University of Medical Sciences

Full name of responsible person

Mohsen Vosough

Position

student

Latest degree

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Other areas of specialty/work

Dentistry

Street address

Chalo village - Shirvan - North Khorasan

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Person responsible for updating data

Contact

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

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is 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

Yes - There is a plan to make this available

Title and more details about the data/document

The total data of people after becoming unidentified people is shareable- Study protocol - Statistical analysis - clinical reports of study - The codes used in the analysis - data classification system - can be published after the end of the study.

When the data will become available and for how long

Start of access period since 1399

To whom data/document is available

All people are allowed

Under which criteria data/document could be used

Only for studies and researches

From where data/document is obtainable

Mohsen Vosough- Chalo Village-Shirvan City-North Khorasan-telephon 09360379611- javad.snm68@gmail.com

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

Request by call or email- one week after call or email

Comments