Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 recieves 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 recieves 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
Bojourd
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 Jahad 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

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 updating data

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

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