Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Evaluation of the effect a herbal lozenge tablet containing ginger, green tea, hollyhock, and mallow and on saliva secretion by measuring the difference in the weight of secreted saliva before and after taking the pill; in healthy volunteers.

Protocol summary

Study aim
Sensory evaluation of a herbal lozenge containing green tea, ginger, marshmallow, and hollyhock and its effect on salivary secretion in healthy volunteers

Design
The clinical trial has no control group and no blinding, it is phase 2 clinical trial on 25 healthy volunteers.

Settings and conduct
The place of study is the Alborz Faculty Of Pharmacy laboratory. By putting cotton in the volunteer's mouth and weighing it, the amount of saliva secreted before and after taking the lozenge is measured and then compared.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Participants must be 18 years old or older. And people over 60 years old or older should not participate in the study; Candidates should not be patient, especially with diseases related to the salivary glands and oral mucosa; Participants should not have a dry mouth or dry eyes; Participants must be able to read, complete, and sign the consent form. They should also be able to understand and answer the questionnaire. Exclusion criteria: Intolerance of taking pills during the test and unwillingness to continue working; People who answer "yes" to the question about dryness. These people are considered "positive" for dry mouth; Lactating women and pregnant women; Participants who complain of dry mouth or dry eyes; Patients with oral lesions or other contact sensitivities; Patients suffering from autoimmune diseases; People with acute or chronic use of drugs that cause dry mouth; Patients undergoing radiotherapy; People with chronic diseases, if they are not well controlled; People with HIV, hepatitis B, or hepatitis C infection

Intervention groups
Volunteers receive the lozenge, and their saliva secretion is measured before and after receiving the lozenge and then compared.

Main outcome variables
Organoleptic characteristics of the lozenge; the effect of the lozenge on the amount of saliva secretion

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20221229056981N1**
Registration date: **2023-04-15, 1402/01/26**
Registration timing: **prospective**

Last update: **2023-04-15, 1402/01/26**
Update count: **0**

Registration date
2023-04-15, 1402/01/26

Registrant information

Name
Mobina Shabani

Name of organization / entity
The Alborz University of Medical Science

Country
Iran (Islamic Republic of)

Phone
+98 21 4463 1775

Email address
mbnsh24@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date

2023-04-24, 1402/02/04

Expected recruitment end date

2023-07-31, 1402/05/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect a herbal lozenge tablet containing ginger, green tea, hollyhock, and mallow and on saliva secretion by measuring the difference in the weight of secreted saliva before and after taking the pill; in healthy volunteers.

Public title

Evaluation of the effect a herbal lozenge tablet containing ginger, green tea, hollyhock, and mallow and on saliva secretion in healthy volunteers.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

1. Participants should be 18 years old or older. And people over 60 years old or older should not participate in the study. 2. Candidates should not be patient, especially diseases which are regarded to salivary glands and oral mucosa. 3. Participants should not have dry mouth or dry eyes. 4. Participants must be able to read, complete and sign the consent form. They should also be able to understand and answer the questionnaire.

Exclusion criteria:

1. Intolerance to taking pills during the test and unwillingness to continue working. 2. People who answer "yes" to the questions about dryness. These people are considered "positive" for dry mouth and cannot participate in the study. 3. Lactating women and pregnant women. 4. Participants who complain of dry mouth or dry eyes. 5. Patients with oral lesions or other contact sensitivities. 6. Patients suffering from autoimmune diseases such as Sjogren's syndrome, rheumatoid arthritis, systemic lupus erythematosus or progressive systemic sclerosis, because people with these autoimmune inflammatory diseases show persistent dry mouth. 7. People with acute or chronic use of drugs that cause dry mouth. Which includes drugs such as antihistamines, antipsychotics, antidepressants and etc. 8. Patients undergoing radiotherapy (mainly for the treatment of head and neck cancer). 9. People with chronic disease, if it is not well controlled. 10. People with HIV, hepatitis B or hepatitis C infection.

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **25**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Alborz University of Medical Sciences

Street address

Deputy of research and technology, Saffarian Alley, Golshahr Ave.

City

Karaj

Province

Alborz

Postal code

3198764653

Approval date

2022-11-12, 1401/08/21

Ethics committee reference number

IR.ABZUMS.REC.1401.250

Health conditions studied

1

Description of health condition studied

Xerostomia

ICD-10 code

K11.7

ICD-10 code description

Disturbances of salivary secretion

Primary outcomes

1

Description

The amount of saliva secretion

Timepoint

Before and after taking the lozenge

Method of measurement

By cotton weighing. In this way, before taking the lozenge, cotton it is placed in the volunteer's mouth and then it is weighed. The same process is repeated after

taking the lozenge. Then, the difference in the weight of the cottons, which shows the increase in saliva secretion, is calculated.

2

Description
Organoleptic characteristics
Timepoint
Immediately after taking the pill
Method of measurement
Statistical analysis is done based on scoring the questionnaire regarding organoleptic characteristics. The questionnaire is evaluated in the form of scoring. Scores are analyzed statistically by Anova method.

Secondary outcomes

empty

Intervention groups

1

Description
First intervention group: The lozenge used contains 500 mg of xylitol, 200 mg of green tea extract, 200 mg of ginger extract, 100 mg of marshmallow extract, and 100 mg of cheese extract. This lozenge was prepared in the laboratory of Alborz University of Medical Sciences. Two pre-weighed cotton rolls are placed on each side of the roof of the person's mouth. Then the cotton rolls are taken out and weighed again. In the second step, we perform all these steps after taking the lozenge and compare the results. The second intervention group: in this evaluation, after taking the lozenge, the volunteer will evaluate the sensory characteristics using the 5-point hedonic method by completing the evaluation questionnaire in the form of scoring.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Alborz University Of Medical Science
Full name of responsible person
Mohammad Mahdi Ahmadian-Attari
Street address
School of Pharmacy, Next to Imam Ali Hospital, Valiasr Street, Shora Blvd.
City
Karaj
Province
Alborz
Postal code
3154686689
Phone
+98 26 3256 7175
Email
ahmadian.attari@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Alborz University Of Medical Science
Full name of responsible person
Razieh Lotfi
Street address
Deputy of research and technology, Saffarian Alley, Golshahr Ave.
City
Karaj
Province
Alborz
Postal code
3198764653
Phone
+98 26 3464 3705
Fax
Email
raziehlotfi@abzums.ac.ir
Web page address
https://research.abzums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Alborz University Of Medical Science
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
Alborz University of Medical Sciences
Full name of responsible person
Mohammad Mahdi Ahmadian-Attari
Position
Assistant professor
Latest degree
Ph.D.
Other areas of specialty/work
Medical Pharmacy
Street address
School of Pharmacy, Next to Imam Ali Hospital,

Valiasr Street, Shora Blvd.
City
Karaj
Province
Alborz
Postal code
3154686689
Phone
+98 26 3256 7175
Email
ahmadian.attari@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Alborz University of Medical Science
Full name of responsible person
Mohammad Mahdi Ahmadian-Attari
Position
Assistant professor
Latest degree
Ph.D.
Other areas of specialty/work
Medical Pharmacy
Street address
School of Pharmacy, Next to Imam Ali Hospital, Valiasr Street, Shora Blvd.
City
Karaj
Province
Alborz
Postal code
3154686689
Phone
+98 26 3256 7175
Fax
Email
ahmadian.attari@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
The Alborz University of Medical Science
Full name of responsible person
Mobina Shabani
Position
Student
Latest degree
A Level or less
Other areas of specialty/work
Medical Pharmacy
Street address
East ground floor, First entrance, 6th block, Apadana Town, Azadi Square
City
Tehran
Province
Tehran
Postal code
1391814714
Phone
+98 21 4463 1775
Fax
Email
Mbnsh24@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
No - There is not a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available
Title and more details about the data/document
All of the collected data and information related to the main outcome or similar can be shared, for example, data related to the effect of the lozenge on the amount of saliva secretion and data related to the organoleptic profile of the lozenge. These data will be published in the form of article.
When the data will become available and for how long
The access is available since1402. After the end of the study and publication of data.
To whom data/document is available
All academic and industry researchers can receive the data without the names of the participants and respecting ethical principles.
Under which criteria data/document could be used
Receiving the data depends on observing ethics in research and maintaining confidentiality, as well as observing the rights of the author regarding the ownership of the data.
From where data/document is obtainable
By corresponding author's email. And also referring to the article or thesis. The thesis is available in the library of Alborz Faculty of Pharmacy .
What processes are involved for a request to access data/document
By sending email and also receive the article or read the thesis in Alborz Pharmacy School.
Comments