Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Investigating the effect of blackberry syrup on reducing hypertrophy of tonsils and its clinical symptoms in patients aged 5 to 15 years

Protocol summary

Study aim

Explaining tonsil enlargement in Persian medicine and study the effect of blackberry paste on tonsil hypertrophy

Design

The clinical trial is two-blind and random. The random assignment of patients to intervention and control is done by the method of quadruple random blocks and by a statistical consultant. 72 envelopes are prepared and in each envelope, the letter A or B is placed and will be numbered from 1 to 72. The letter A will belong to the intervention group and the letter B will belong to the control group. The sample size in each group is 36 people and in total 72 people.

Settings and conduct

Clinical trials in the field of traditional medicine will be performed in patients of Toobi Clinic in Sari and Bouali Specialized Clinic in Sari. Random assignment of patients to intervention and control is done by a statistician who does not have access to patients. There is no medicine or placebo inside.

Participants/Inclusion and exclusion criteria

Conditions for patients with tonsillar hypertrophy older than 5 years and younger than 15 years who want to participate in this project and use traditional medicine products. Withdrawal conditions include acute tonsillitis, tonsillar abscess, unstable clinical condition, systemic corticosteroid use or antibiotics from 4 weeks ago, allergy to blackberry and honey, symptoms of incompatibility with consumption of blackberry product, inability to communicate and unwillingness of the patient to Continuation of cooperation in the study

Intervention groups

Includes intervention and control groups. In the intervention group, patients were given blackberry oral syrup for 4 weeks and the control group was given placebo for 4 weeks.

Main outcome variables

Tonsil size, Dysphagia, nasal speech, mouth breathing during sleep, snoring at night before and 4 weeks after intervention; Tonsillectomy was performed 4 and 12 weeks after the intervention

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220315054291N1**
Registration date: **2022-08-10, 1401/05/19**
Registration timing: **registered_while_recruiting**

Last update: **2022-08-10, 1401/05/19**
Update count: **0**

Registration date

2022-08-10, 1401/05/19

Registrant information

Name

Mohammadali Pourabbasi

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-07-23, 1401/05/01

Expected recruitment end date

2023-05-21, 1402/02/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of blackberry syrup on reducing hypertrophy of tonsils and its clinical symptoms in patients aged 5 to 15 years

Public title

Effect of blackberry syrup on tonsil hypertrophy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with chronic tonsillar hypertrophy Being in the age range of 5 to 15 years Willingness to participate in this research Tendency to consume traditional medicine medicinal products

Exclusion criteria:

Having Acute tonsillitis Having tonsillar abscess Having unstable clinical conditions Take systemic corticosteroids 4 weeks before the intervention Take antibiotics 4 weeks before the intervention Sensitivity to blackberry Sensitivity to honey Demonstrate signs of incompatibility with the consumption of blackberry syrup Inability to communicate Patient's unwillingness to continue cooperating in the study

Age

From **5 years** old to **15 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **72**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, random assignment of patients to experimental and control groups will be done using the quadruple random blocks method. We know that the number of possible blocks of four of the two letters A and B is equal to 6; As follows: (AABB-ABAB-ABBA-BAAB-BABA-BBAA) If we denote them by the numbers 1 to 6, to randomly assign them using blocks of 4, first by throwing 18 regular hexagons, a random sequence of numbers 1 to 6 into 18 blocks of 4 from the sub-generated blocks Will: In the desired sequence, there will be 36 letters from each letter A and B. According to the above blocks, 72 envelopes will be prepared and in each envelope, the letter A or B will be placed and will be numbered from 1 to 72. The person delivering the envelopes to the patients does not know what is inside. The production of a random sequence is done by a statistics and methodology consultant who does not have access to patients and only he knows what is in each issue. Patients who received the letter A will be in the intervention group and patients who received the letter B will be in the control group.

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients with tonsillar hypertrophy are randomly divided into intervention and placebo groups according to the inclusion criteria. After random sampling and determining whether the patient belongs to the intervention or control group, it is justified by the clinical caregiver and The required training is provided and the package containing the guide and medication brochure will be delivered to patients. In addition to oral explanations about how to study, how to use the drug, the amount and time of use and frequency and duration of treatment are explained. Intervention and control groups will be performed using the quadruple random blocks method. According to the above blocks, 72 envelopes will be prepared and in each envelope, the letter A or B will be placed and will be numbered from 1 to 72. The person delivering the envelopes to the patients does not know what is inside. The production of a random sequence is done only by a "statistics and methodology consultant" who does not have access to patients and only he knows what is in each issue. Patients who received the letter A in the intervention group and patients who received the letter B. All patients will not be aware of the type of drug in the package, including one of the placebo or the main drug under study.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mazandaran University of Medical Sciences

Street address

Khazar Boulevard, next to Touba Clinic, Faculty of Traditional Medicine, second floor

City

Sari

Province

Mazandaran

Postal code

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Approval date

2022-03-19, 1400/12/28

Ethics committee reference number

IR.MAZUMS..REC.1400.11548

Health conditions studied

1

Description of health condition studied
Tonsil hypertrophy
ICD-10 code
J35.1
ICD-10 code description
Hypertrophy of tonsils

Primary outcomes

1

Description
The size of the tonsils according to the Brodsky scale
Timepoint
Beginning of the study (before the intervention)
Method of measurement
Tonsil size classification with Brodsky scale

Secondary outcomes

1

Description
The size of the tonsils according to the Brodsky scale
Timepoint
4 weeks after intervention (after taking blackberry syrup or placebo)
Method of measurement
Tonsil size classification with Brodsky scale

Intervention groups

1

Description
Intervention group: patients slowly eat blackberry syrup for 4 weeks by taking one tablespoon of 5 cc in patients three times a day including morning, noon and night (about 10 seconds) should be kept in the mouth and not swallowed quickly to provide more contact between the syrup and the pharynx and tonsils. Blackberries and 30% honey are prepared by a reputable pharmaceutical factory under sterile conditions and during the pharmaceutical and pharmaceutical processing stages in 120 cc jars. Honey is used as a reformer of blackberries in this product. Blackberries are rich in polyphenols. Among them is anthocyanin, which is a strong antioxidant. Anthocyanin has strong antioxidant, anti-proliferative, and anti-inflammatory properties that can be used in the treatment or prevention of inflammatory diseases and prevent the inappropriate growth and proliferation of cells. Patients are treated by the assistant of traditional medicine. justified and provide the necessary training and recommendations Parents of the patients are explained and trained on how to conduct the study, how to use the drug under study. In addition, during one month, they should observe the necessary precautions in case of tonsillitis, including avoiding drinking very cold liquids, ice water, consuming vinegar, and pickles. Outside the house and washing hands and face after entering the house will be emphasized. In addition to providing verbal explanations, a brochure containing necessary recommendations has been prepared and will be delivered to the patients along with the medicine.
Category
Treatment - Drugs

2

Description
Control group: For 4 weeks, patients slowly eat the placebo oral syrup by taking one tablespoon of 5 cc, three times a day including morning, noon and night after meals, and it will be recommended to take the syrup a little longer (about 10 seconds) should be kept in the mouth and not swallowed quickly. Placebo oral syrup is a combination of water, glucose and permitted food coloring, which is prepared by a reputable pharmaceutical factory under sterile conditions and during the pharmaceutical and pharmaceutical processing stages in 120 cc bottles.The patients are justified by the traditional medicine assistant and the necessary training and recommendations are provided. The parents of the patients are taught that during one month, the necessary precautions for tonsillitis, including avoiding drinking very cold liquids, ice water, and consuming vinegar Also, it will be emphasized on the necessity of following health protocols in order to prevent the occurrence of infections such as colds, including wearing a mask outside the house and washing hands and face after entering the house. It includes the necessary recommendations that will be delivered to the patients along with the medicine Headed.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Touba Sari Specialized Clinic
Full name of responsible person
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2

Recruitment center

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Full name of responsible person
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
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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
Mazandaran 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
Mazandaran University of Medical Sciences

Full name of responsible person
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Position
Profesor asistente

Latest degree
Ph.D.

Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available