Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Evaluating the Efficacy of Royal Jelly Compared to Placebo in Improving Tinnitus in Affected Patients: Randomized controlled trial

Protocol summary

Study aim

To evaluate the efficacy of oral royal jelly in reducing tinnitus severity in patients diagnosed with subjective tinnitus.

Design

This is a randomized, double-blind, placebo-controlled, parallel-group phase II clinical trial. A total of 60 participants (30 per group) will be enrolled. Randomization will be performed using block randomization (blocks of four) with the Rand function in Microsoft Excel.

Settings and conduct

The study will be conducted in 2025 at Al-Zahra Hospital in Isfahan and Ayatollah Kashani Hospital in Kashan. Both participants and assessors will be blinded. Syrups will be packaged identically and labeled with anonymized codes. Participants will be assessed at baseline and at 3, 6, and 12 weeks after the intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: confirmed diagnosis of tinnitus by an ENT specialist, no prior history of hypersensitivity to royal jelly, absence of psychiatric disorders, and no history of hearing aid use or ototoxic medications. Exclusion criteria: unwillingness to continue participation, hypersensitivity to royal jelly, irregular medication use, concurrent use of other therapeutic strategies, and presence of acoustic neuroma or other organic auditory nerve lesions.

Intervention groups

The intervention group will receive oral royal jelly syrup daily for 30 days. The control group will receive a placebo syrup matched in color, taste, and viscosity without the active ingredient.

Main outcome variables

Tinnitus severity measured using the Tinnitus Handicap Inventory (THI) at weeks 0, 3, 6, and 12; changes in THI score from baseline.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240327061371N3**
Registration date: **2025-05-26, 1404/03/05**
Registration timing: **prospective**

Last update: **2025-05-26, 1404/03/05**
Update count: **0**

Registration date

2025-05-26, 1404/03/05

Registrant information

Name

Afrooz Eshaghian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-05-31, 1404/03/10

Expected recruitment end date

2025-08-23, 1404/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the Efficacy of Royal Jelly Compared to Placebo in Improving Tinnitus in Affected Patients: Randomized controlled trial

Public title
Studying the effect of royal jelly on the treatment of tinnitus

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Tinnitus and confirmation of the condition based on clinical diagnosis by an otolaryngologist and based on audiometry results (audiometry including tinnitus frequency) No history of allergy to royal jelly. No history of mental disorders or use of stimulant medications Not having hearing loss or deafness or using hearing aids Avoid taking ototoxic medications.

Exclusion criteria:
Concomitant use of other treatment strategies Unwillingness to participate in the study Allergy to royal jelly Organic causes, if diagnosed, such as Meniere's disease and acoustic neuroma Unilateral Tinnitus

Age
No age limit

Gender
Both

Phase
2

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
To ensure equal distribution of patients to the treatment and placebo groups and to maintain balance during the randomization process, a block randomization method will be used. The block size is chosen as 4, which is a multiple of the number of groups. For a block of four, the combinations AABB, ABAB, ABBA, BBAA, BABA, BAAB will be defined. The order of the blocks will be randomized using Excel software. Fifteen blocks will be required to allocate 60 patients (30 in each group).These 15 blocks are randomly selected and will be repeated as needed. Patients are then assigned sequentially based on the random order of the blocks. For example, the first four patients are assigned according to the first block allocation, the next four patients according to the second block, and so on until all 60 patients are assigned.

Blinding (investigator's opinion)
Double blinded

Blinding description
To ensure a double-blind study, both patients and investigators will be unaware of group assignments (royal jelly or placebo). Group A will receive 10 cc of royal jelly syrup daily for 30 days. Group B will receive 10 cc of placebo syrup following the same schedule. The placebo syrup is formulated to match the active drug in color, odor, and viscosity, and contains distilled water as the base, sucrose as a sweetener, flavoring, food coloring, and, if necessary, an approved preservative (e.g., sodium benzoate). The placebo formulation and preparation will be conducted by a specialized pharmacist in compliance with Good Manufacturing Practice (GMP) standards. The placebo syrup will be packaged and labeled in containers and boxes identical to those of the active drug and coded by an independent pharmacist. The code key will remain with the pharmacist until the study’s completion to prevent bias.

Placebo
Used

Assignment
Parallel

Other design features
Patients were assessed for tinnitus severity before treatment and at 1, 3, 6, and 12 weeks after treatment using the THI questionnaire.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Isfahan University of Medical Sciences

Street address
Building No. 4, Hezar Jarib Street, Isfahan University of Medical Sciences and Health Services, Vice-Chancellery for Research and Technology

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Isfahan

Province
Isfehan

Postal code
8174673461

Approval date
2025-05-11, 1404/02/21

Ethics committee reference number
IR.MUI.MED.REC.1404.074

Health conditions studied

1

Description of health condition studied
Tinnitus

ICD-10 code
H93.1

ICD-10 code description
Tinnitus

Primary outcomes

1

Description
Tinnitus severity based on the total score of the “Tinnitus Handicap Inventory” questionnaire, which assesses the impact of tinnitus on patients’ daily life.
Timepoint
Tinnitus severity score will be measured at baseline (before the intervention) and at weeks 1, 3, 6, and 12 after the start of royal jelly syrup consumption.
Method of measurement
Tinnitus severity will be assessed using the validated Persian version of the “Tinnitus Handicap Inventory” questionnaire, consisting of 25 questions rated on a five-point Likert scale.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Participants in this group will receive an oral syrup containing royal jelly once daily for 30 consecutive days. Each dose consists of 10 milliliters of syrup per day. The formulation includes pure royal jelly as the active ingredient, distilled water, an oral sweetener (such as sucrose), and approved edible flavoring and coloring agents. The syrup will be manufactured under GMP conditions and packaged identically to the placebo to maintain double-blinding. The detailed composition and preparation process will be supervised and verified by the study pharmacist.
Category
Treatment - Drugs

2

Description
Control group: Participants in this group will receive a placebo syrup once daily for 30 days. The placebo formulation consists of distilled water, an oral sweetener (such as sucrose), edible coloring and flavoring agents to match the taste, color, and viscosity of the active syrup. The placebo will be prepared under Good Manufacturing Practice (GMP) standards and packaged identically to the active product to ensure blinding.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Alzahra hospital
Full name of responsible person
Ali Mahmudi
Street address
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https://alzahra.mui.ac.ir/

2

Recruitment center
Name of 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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Web page address
https://research.mui.ac.ir/fa/moaven/moarefi
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Esfahan 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
Esfahan University of Medical Sciences
Full name of responsible person
Afrooz Eshaghian
Position
Assistant professsor
Latest degree
Specialist
Other areas of specialty/work
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Person responsible for scientific inquiries

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Specialist
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Person responsible for updating data

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Full name of responsible person
Afrooz Eshaghian
Position
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Latest degree
Specialist
Other areas of specialty/work
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Street address
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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
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
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

Study Protocol: Full study design and methodology document. Statistical Analysis Plan: Detailed plan of pre-specified statistical methods. Clinical Study Report: Structured summary of trial results and findings. Statistical Code: Scripts used for data analysis (e.g., SPSS, R). Data Dictionary: Descriptions of dataset variables, formats, and coding. All shared documents will exclude personally identifiable information. No individual-level data will be shared.

When the data will become available and for how long

Access will be granted 6 months after publication of study results and will remain available for 5 years thereafter.

To whom data/document is available

Qualified researchers affiliated with academic institutions, public health organizations, or regulatory agencies may submit requests.

Under which criteria data/document could be used

Data and documents may be used for non-commercial, academic purposes such as secondary analysis or meta-analysis. All applicants must provide a brief proposal outlining the intended use. Data sharing is conditional on the signing of a data use agreement ensuring ethical and legal compliance.

From where data/document is obtainable

Requests should be directed to: Dr. Afrooz Eshagh Principal Investigator Email: afroozeshaghian@med.mui.ac.ir Affiliation: Isfahan University of Medical Sciences

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

Applicants should submit a formal request including a research proposal, institutional affiliation, and intended analysis. The review process will take approximately 2 to 4 weeks, and decisions will be communicated via email. If approved, documents will be shared via secure cloud storage or institutional email.

Comments

The research team reserves the right to deny requests that do not meet ethical or scientific standards. No financial charge will be applied for access to documents.