Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Evaluation of the Effect of Ganoderma lucidum syrup Consumption on Hemodynamic Changes Before and After maxillary molar Tooth Extraction

Protocol summary

Study aim

Evaluation of the Effect of Ganoderma lucidum syrup Consumption on Hemodynamic Changes Before and After maxillary molar Tooth Extraction in Patients Referred to the School of Dentistry, Isfahan University of Medical Sciences

Design

Randomized double blimde parallel-group controlled clinical trial will be conducted in 40 patients with three assessment . randomization will be performed using a random number table

Settings and conduct

This study will be conducted to evaluate the efficacy of a Ganoderma lucidum extract solution on hemodynamic changes and stress levels in patients undergoing maxillary molar extraction. Both the clinician and the patients will be blinded to the type of solution administered. Patients will receive either the Ganoderma lucidum extract syrup or a placebo, and their hemodynamic parameters will be assessed at three time points. In addition, to qualitatively assess patients' dental anxiety, the Dental Anxiety Inventory (DAI) questionnaire will be administered to the participants.

Participants/Inclusion and exclusion criteria

entry criteria: ASA I Health status exit criteria: more than 1 anesthesia medicine cartridge needed - surgery intervention needed

Intervention groups

ganoderma lucidum syrup - placebo with same taste and smell

Main outcome variables

Heart rate, blood glucose level, systolic and diastolic blood pressure, and stress indices will be measured in both groups before and after tooth extraction. Assessments will be performed at three time points: before administration of the syrup, 30 minutes after administration, and 1 minute after tooth extraction.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260825070789N1**
Registration date: **2026-09-27, 1405/07/05**
Registration timing: **registered_while_recruiting**

Last update: **2026-09-27, 1405/07/05**
Update count: **0**

Registration date

2026-09-27, 1405/07/05

Registrant information

Name

Erfan Hossein poor

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3777 1695

Email address

erfanhp46@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2026-09-24, 1405/07/02

Expected recruitment end date

2026-10-10, 1405/07/18

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the Effect of Ganoderma lucidum syrup Consumption on Hemodynamic Changes Before and After maxillary molar Tooth Extraction

Public title
Evaluation of the Effect of Ganoderma lucidum syrup Consumption on Hemodynamic Changes
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
patients with ASA I health status who require simple extraction of maxillary molar
Exclusion criteria:
patients with ASA II, ASA III, ASA IV health status Patients requiring complex surgical extraction of a molar tooth
Age
From **18 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
Simple randomization will be used to allocate participants to the study and control groups in a 1:1 ratio, with the individual participant serving as the unit of randomization. The random allocation sequence will be generated prior to the initiation of the study and will be held by an individual other than the physician responsible for the assessment and treatment of the patients. Information regarding group allocation will be maintained in coded form, and the allocation code assigned to each participant will be kept confidential. The allocation code for each participant will remain concealed from the researcher until completion of the tooth extraction procedure. The researcher will have no involvement in determining the group assignment of the patients. Group allocation will be performed after enrollment in the study according to the predetermined random allocation sequence. Random allocation will be performed using a random number table.
Blinding (investigator's opinion)
Double blinded
Blinding description
The allocation of the syrup or placebo will be randomized and concealed from both the participants and the clinician throughout the study and both parties will remain blinded to the type of syrup received until the completion of the dental extraction and the assessment of hemodynamic change at the third time point (double-blind design)
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committee of the Faculties of Dentistry, Health, and New Medical Technologies, Isfah
Street address
Hezar Jerib St. Isfahan University of Medical Sciences,Isfahan
City
esfahan
Province
Isfehan
Postal code
8174673461
Approval date
2026-07-25, 1405/05/03
Ethics committee reference number
IR.MUI.DHMT.REC.1405.080

Health conditions studied

1

Description of health condition studied
stress - hemodynamic changes - ganoderma lucidum
ICD-10 code
K08.9
ICD-10 code description
Disorder of teeth and supporting structures, unspecified

Primary outcomes

1

Description
heart rate
Timepoint
1.before intervention 2. 30 minutes after taking syrup 3. 1 minute after tooth extraction
Method of measurement
digital Heart rate and blood pressure monitoring device

2

Description
blood pressure
Timepoint
1.before intervention 2. 30 minutes after taking syrup 3. 1 minute after tooth extraction
Method of measurement
digital Heart rate and blood pressure monitoring device

3

Description
blood sugar
Timepoint
1.before intervention 2. 30 minutes after taking syrup 3. 1 minute after tooth extraction
Method of measurement
digital blood sugar monitoring device

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: receiving 10 cc syrup contained with 1500 mg of extracted ganoderma lucidom mushroom and artificial sweetener 30 minutes before tooth extraction
Category
Other

2

Description
Control group: placebo with same color taste and odor
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Medical university of esfahan dentistry faculty
Full name of responsible person
Milad Etemadi
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Grant name
121200000 Rials
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
Erfan Hossein poor
Position
Student
Latest degree
Medical doctor
Other areas of specialty/work
Dentistry
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Person responsible for scientific inquiries

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Person responsible for updating data

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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 extractable study data will include participants' sex, age, the tooth number undergoing simple extraction, hemodynamic changes in the intervention and control groups, and their scores on the dental anxiety questionnaire. All data will be shareable after de-indentification of the participants.

When the data will become available and for how long
the data access period will begin 3 months after publiction of the study results.

To whom data/document is available
the data will be made available only to researchers affilated with academic and scientific institutions

Under which criteria data/document could be used
for the purpose of conducting studies on dental anxiety and herbal compounds on other populations

From where data/document is obtainable
Milad Etemadi - etemadi@dnt.mui.ac.ir Erfan hossein poor - erfanhp46@gmail.com

What processes are involved for a request to access data/document
Individuals seeking access to the information and data collected in this study may submit their request to the Email adresses provided.

Comments