

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The effect of a period of swimming endurance training with supplementation of Ajwain on serum levels of some inflammatory factors and liver enzymes in male students

Protocol summary

Study aim

Evaluation of the simultaneous effects of endurance swimming exercises and supplementation of women on immune and hepatic inflammatory mediators

Design

60 people will be selected as a statistical sample. Subjects will be divided into four groups: Ajwain + Swimming Endurance Exercise / Ajwain / Swimming Endurance Exercise / Control. The training program will include endurance swimming and supplemental capsules for a period of 10-12 weeks. Serum concentrations of ALT, AST, CRP, and TNF α were measured in two-time stages.

Settings and conduct

We do not have blindness. According to the training program, it is probably done in the university pool. Ajwain is supplemented as a capsule according to the pilot program.

Participants/Inclusion and exclusion criteria

Inclusion criteria: No history of disease / No allergy to supplements / No high blood pressure / No heart disease
Exclusion criteria: Existence of underlying disease / being an athlete / taking any supplements

Intervention groups

Groups : Exercise Training Exercise and supplement of Ajwain Supplement of Ajwain

Main outcome variables

Possible changes in serum levels of ALT and AST enzymes and inflammatory mediators CRP and TNF α

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180805040704N1**
Registration date: **2021-07-16, 1400/04/25**

Registration timing: **retrospective**

Last update: **2021-07-16, 1400/04/25**

Update count: **0**

Registration date

2021-07-16, 1400/04/25

Registrant information

Name

Farah Nameni

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8843 6932

Email address

dastavard96@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-06-19, 1400/03/29

Expected recruitment end date

2021-06-21, 1400/03/31

Actual recruitment start date

2021-06-19, 1400/03/29

Actual recruitment end date

2021-06-21, 1400/03/31

Trial completion date

2021-06-21, 1400/03/31

Scientific title

The effect of a period of swimming endurance training with supplementation of Ajwain on serum levels of some inflammatory factors and liver enzymes in male students

Public title

The effect of training and Ajwain on some inflammatory

factors and liver enzymes

Purpose
Other

Inclusion/Exclusion criteria
Inclusion criteria:
 Lack of disease history Lack of susceptibility to supplementation Lack of blood pressure Lack of heart disease
Exclusion criteria:
 Lack of disease Lack of susceptibility

Age
From **18 years** old to **25 years** old

Gender
Male

Phase
N/A

Groups that have been masked
No information

Sample size
 Target sample size: **60**
 Actual sample size reached: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
 First, all the names of all male students in the university are extracted Then, according to the age conditions and lack of training and non-supplementation, new people are registered After confirming the state of health and the absence of disease, their number is determined According to the required number of considered samples (60 people) are selected by simple random method Then, in the final stage, these 60 people will be grouped based on a simple random sampling method

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of the Faculty of Medical Sciences,
Islamic Azad University, Varamin Pishva Branch

Street address

Tehran - Pishva city, Naghsh Jahan town, Islamic Azad
University, Varamin branch - Pishva

City

Pishva

Province

Tehran

Postal code

33817-74895

Approval date

2019-06-16, 1398/03/26

Ethics committee reference number

IR.IAU.VARAMIN.REC.1398.007

Health conditions studied

1

Description of health condition studied

We do not have a disease

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Investigating the effect of exercise and Ajwain on the rate of change: CRP/ TNFa/ ALT/ AST

Timepoint

Before the research period, after the research period

Method of measurement

Special Kits

Secondary outcomes

1

Description

Possible changes in inflammatory and immune mediators in serum (TNFα, CRP, HSP70)

Timepoint

1:Before the start of the research protocol (swimming endurance training and supplementation) 2: Immediately after the end of the research protocol (swimming endurance training and supplementation)

Method of measurement

Taking blood samples in two time periods before and after the research protocol, evaluation of inflammatory and immune dependent variables using special kits and laboratory methods such as ELYZA

Intervention groups

1

Description

Exercise intervention group 1:They only do swimming endurance training

Category

N/A

2

Description

Intervention group2: Consumption of Ajwain : They only take supplements

Category

N/A

3

Description

Intervention group3 : Swimming endurance training and supplementation

Category

N/A

4

Description

Control group : It has neither exercise nor supplementation

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

IAU.VARAMIN.PISHVA

Full name of responsible person

Mohammad Aiini

Street address

Pishva city, Naghsh Jahan town, Islamic Azad University, Varamin branch - Pishva

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Mohammad Alini

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mohammad.aeini67@gmail.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Islamic Azad University

Proportion provided by this source

1

Public or private sector

Private

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

Islamic Azad University

Full name of responsible person

Mohammad Aiini

Position

Wushu Coach

Latest degree

Bachelor

Other areas of specialty/work

Nutrition

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Person responsible for scientific inquiries

Contact

Name of organization / entity

IAU.Varamin

Full name of responsible person

Farah Nameni

Position

Assis. Prof.

Latest degree

Ph.D.

Other areas of specialty/work

Sport Medicine

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Person responsible for updating data

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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

Not applicable

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