Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The effect of lemon balm on oxidative stress and antioxidant response in amateur adolescent football players

Protocol summary

Study aim
This study aimed to investigate the effect of consuming one week of dried lemon balm extract on oxidative stress and antioxidant response in amateur adolescent football players after a football match.

Design
They will be randomly assigned to either the supplementation group or the placebo group, using computer-generated sequences,

Settings and conduct
Participants will visit the physiology laboratory on four occasions. The first session is designed to measure their anthropometric characteristics (stature, weight, body mass, and percentage of body fat) and evaluate basic levels of MDA, TAC, GPx, SOD, and CAT. The second session will be an assessment of MDA, TAC, GPx, SOD, and CAT before the football match, and the third and fourth sessions will measure MDA, TAC, GPx, SOD, and CAT 30 minutes and 90 minutes after the football match, respectively. Participants completed a food diary 72 hours before their first session and will repeat this diet before the second session. They also refrain from consuming antioxidant supplements, drinking alcohol, and engaging in any exercise 72 hours before the first session and during the week of intervention.

Participants/Inclusion and exclusion criteria
Soccer players who have to have at least one year of experience playing soccer in provincial or national competitions and trained at least six hours per week. They will be excluded if they have had any injuries, illnesses, or infectious diseases or if they have consumed steroidal or non-steroidal anti-inflammatory drugs or nutritional supplements such as vitamins E and C in the last six months.

Intervention groups
This group will receive 1.5 g/day of dried extract of lemon balm

Main outcome variables
Total Antioxidant Capacity; malondialdehyde; catalase; glutathione peroxidase; superoxide dismutase

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20240328061378N1**
Registration date: **2024-12-08, 1403/09/18**
Registration timing: **retrospective**

Last update: **2024-12-08, 1403/09/18**
Update count: **0**

Registration date
2024-12-08, 1403/09/18

Registrant information

Name
Ali Nejatian Hoseinpour

Name of organization / entity
Allameh Tabataba'i University

Country
Iran (Islamic Republic of)

Phone
+98 51 3729 3354

Email address
ali_nejatiyan@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-02-19, 1402/11/30

Expected recruitment end date
2024-04-18, 1403/01/30

Actual recruitment start date
2024-06-21, 1403/04/01

Actual recruitment end date
2024-08-20, 1403/05/30

Trial completion date
empty

Scientific title
The effect of lemon balm on oxidative stress and antioxidant response in amateur adolescent football players

Public title
A Soccer Match Increases Antioxidant Irrespective of Lemon Balm Supplementation

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
Soccer players who have to have at least one year of experience playing soccer in provincial or national competitions and trained at least six hours per week.

Exclusion criteria:
They will be excluded if they have had any injuries, illnesses, or infectious diseases or if they have consumed steroidal or non-steroidal anti-inflammatory drugs or nutritional supplements such as vitamins E and C in the last six months.

Age
From **10 years** old to **19 years** old

Gender
Male

Phase
0

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size
Target sample size: **20**
Actual sample size reached: **20**

Randomization (investigator's opinion)
Randomized

Randomization description
The study will use a simple randomization method. Participants are randomly assigned into two groups—an intervention group receiving lemon balm and a placebo group. The randomization will be done at the individual level, with each of the 20 soccer players assigned to one of the two groups. A computer-generated sequence will be used to allocate participants to each group randomly. This method provides high precision and reproducibility, minimizing selection bias. The sequence will be generated in a computer system to ensure unpredictability. Allocation concealment will be achieved by keeping this sequence hidden from the researchers and participants until after the intervention is completed.

Blinding (investigator's opinion)
Double blinded

Blinding description
The study is double-blind, meaning that neither the participants nor the researchers (including principal investigators and outcome assessors) will know who will receive the intervention or the placebo. This will be accomplished by using identical capsules for the lemon balm and placebo, thus preventing visual differentiation. The adolescent soccer players will not know whether they are receiving the supplement or placebo. Those responsible for collecting and analyzing the blood samples and performance data will be blinded to group assignments, ensuring unbiased results and principal Investigators will Remain blinded to group allocations during data collection and analysis.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethics Committees of Allameh Tabataba'i University (ATU)

Street address
Floor 13, Block A, Ministry of Health & Medical Education Headquarters, Between Zarafashan & South Falamak, Qods Town, Tehran, Iran.

City
Tehran

Province
Tehran

Postal code
1111111111

Approval date
2023-04-08, 1402/01/19

Ethics committee reference number
IR.ATU.REC.1402.006

Health conditions studied

1

Description of health condition studied
Healthy Adolescent

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Total Antioxidant Capacity

Timepoint
Before and after the supplementation, 30 and 90 minutes after the match

Method of measurement
Biochemical and laboratory methods

2

Description
Superoxide dismutase
Timepoint
Before and after the supplementation, 30 and 90 minutes after the match
Method of measurement
Biochemical and laboratory methods

3

Description
Glutathione peroxidase
Timepoint
Before and after the supplementation, 30 and 90 minutes after the match
Method of measurement
Biochemical and laboratory methods

4

Description
Catalase
Timepoint
Before and after the supplementation, 30 and 90 minutes after the match
Method of measurement
Biochemical and laboratory methods

5

Description
Malondialdehyde
Timepoint
Before and after the supplementation, 30 and 90 minutes after the match
Method of measurement
Biochemical and laboratory methods

Secondary outcomes

empty

Intervention groups

1

Description
Control group: in this group we have not any intervention during the protocol and will consider this group as placebo
Category
Placebo

2

Description
Intervention group: This group will receive 1.5 g/day of dried extract of lemon balm
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Allameh Tabataba'i university
Full name of responsible person
Ali Nejatian Hoseinpour
Street address
Allameh Tabataba'i University, Varzesh Sq., Dehkadeh Olampik, Tehran, Iran.
City
Tehran
Province
Tehran
Postal code
1489684511
Phone
+98 21 4839 0000
Email
ict@atu.ac

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Allameh Tabataba'i University
Full name of responsible person
Ali Nejatian Hoseinpour
Street address
Allameh Tabataba'i University, Varzesh Sq., Dehkadeh Olampik, Tehran, Iran.
City
Tehran
Province
Tehran
Postal code
1489684511
Phone
+98 21 4839 0000
Email
ict@atu.ac
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
دانشگاه علامه طباطبایی
Proportion provided by this source
100
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

Persons

Person responsible for general inquiries

Contact

Name of organization / entity
Allameh Tabataba'i University

Full name of responsible person
Ali Nejatian Hoseinpour

Position
دانشجو

Latest degree
Master

Other areas of specialty/work
Sport Medicine

Street address
Chamran St, Kabiri Tamme, Jantabad Central

City
Tehran

Province
Tehran

Postal code
1111111111

Phone
0098513233354

Email
alinejatiyan70@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Allameh Tabataba'i University

Full name of responsible person
Ali Nejatian Hoseinpour

Position
دانشجو

Latest degree
Master

Other areas of specialty/work
Sport Medicine

Street address
Chamran St, Kabiri Tamme, Jantabad Central

City
Tehran

Province
Tehran

Postal code
1111111111

Phone
0098513233354

Email
alinejatiyan70@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Allameh Tabataba'i University

Full name of responsible person
Ali Nejatian Hoseinpour

Position
دانشجو

Latest degree
Master

Other areas of specialty/work
Sport Medicine

Street address
Chamran St, Kabiri Tamme, Jantabad Central

City
Tehran

Province
Tehran

Postal code
1111111111

Phone
0098513233354

Email
alinejatiyan70@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
No - There is not 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
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
The report will be submitted to the university's research department. Also published as a paper

When the data will become available and for how long
2025

To whom data/document is available
All researchers

Under which criteria data/document could be used
Citing references

From where data/document is obtainable
Scientific bases and Allameh Tabatabai University of Iran

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

Comments