Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Effects of an Iranian traditional medicine product (Ostokhodus Alavi capsule) on the cognitive performance of adolescent female students in Yazd city

Protocol summary

Study aim
Determination of the effect of an Iranian traditional medicine product (Ostokhodus Alavi capsule) on the cognitive performance of adolescent female students in Yazd city in an academic year.

Design
Clinical trial with control group, withe parallel group, double blind, randomized

Settings and conduct
For assessment of cognition function of the participants, the demographic information, Depression-Anxiety-Stress Scale (DASS), Mizaj questioner, Paced Auditory Serial Addition Test (PASAT), and the level of sputum cortisol will be evaluated before and after the intervention. The duration of consumption of capsules will be 6 weeks and the follow-up will be carried out after 4 weeks. The capsules will be given to the students in two sessions separated by three weeks. The follow up is after 4 weeks by taking sputum sample and completion of the DASS and PASAT tests again.

Participants/Inclusion and exclusion criteria
Entrance condition: healthy 16 to 17 years old girls No entrance: diagnosed with psychological disorders

Intervention groups
1.The receivers of Ostokhodus Alavi capsule 2.The receivers of placebo

Main outcome variables
The cognitive measures assessed by Paced Auditory Serial Addition Test are mental health, information processing, sustained attention, mental fatigue. The cortisol level of sputum is also evaluated.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190921044827N1**
Registration date: **2020-04-06, 1399/01/18**
Registration timing: **registered_while_recruiting**

Last update: **2020-04-06, 1399/01/18**
Update count: **0**

Registration date
2020-04-06, 1399/01/18

Registrant information

Name
Samane Tefagh

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 8877 3521

Email address
s.tefagh@sbmu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-10-21, 1398/07/29

Expected recruitment end date
2020-07-20, 1399/04/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effects of an Iranian traditional medicine product (Ostokhodus Alavi capsule) on the cognitive performance of adolescent female students in Yazd city

Public title
Effect of Ostokhodus Alavi capsule on students concentration.
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Healthy 16 to 17 years old girls acknowledgment of parents and students
Exclusion criteria:
Diagnosed with sever depression or anxiety or stress Diagnosed with psychological disorders that interfere with cognition function Low IQ(Low grade in mathematics, science and literature courses) Consumption of herbal or chemical drugs on cognition function at the beginning of the study Sever hearing or movement impairment that interfere with passing the PASAT study
Age
From **16 years** old to **17 years** old
Gender
Female

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **90**
Randomization (investigator's opinion)
Randomized
Randomization description
The drugs and placeboes are labeled by unique randomly-generated codes consisting of two alphabetic letters and one number. During the study, the participants are given medications, according to the order of their arrival and randomization sheets (containing only anonymous codes).
Blinding (investigator's opinion)
Double blinded
Blinding description
The Ostokhodus Alavi and placebo capsules were coded. The participants, researchers, and analyzers were blind. Only the pharmaceutical company is aware of the association between the codes and capsules.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shahid Beheshti University of Medical Sciences
Street address
Shahid Beheshti University of Medical Sciencess, Yaman street
City
Tehran
Province
Tehran
Postal code
1985717443
Approval date
2020-01-26, 1398/11/06
Ethics committee reference number
IR.SBMU.RETECH.REC.1398.771

Health conditions studied

1

Description of health condition studied
cognitive function
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
mental health
Timepoint
Beginning of the study, 3 weeks, 6 weeks and 10 weeks from the beginning of the study
Method of measurement
Paced Auditory serial addition Test(PASAT)

2

Description
average respond time
Timepoint
Beginning of the study, 3 weeks, 6 weeks and 10 weeks from the beginning of the study
Method of measurement
PASAT test

3

Description
sustained attention
Timepoint
Beginning of the study, 3 weeks, 6 weeks and 10 weeks from the beginning of the study
Method of measurement
PASAT test

4

Description
mental fatigue
Timepoint
Beginning of the study, 3 weeks, 6 weeks and 10 weeks from the beginning of the study
Method of measurement
PASAT test

5

Description
sputum cortisol level
Timepoint
Beginning of the study, 6 weeks and 10 weeks from the beginning of the study
Method of measurement
ELISA Kit

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group:Ostokhodus Alavi capsule, Contents: avandula spp., Anacyclus pyrethrum, Polypodium vulgare, Cuscuta spp, Paeonia officinalis, Vitis vinifera, honey, Dose: a 250 mg capsule after breakfast for 6 weeks, Company: Tuba pharmaceutical company
Category
Treatment - Drugs

2

Description
Control group: Placebo capsule, Contents: avicel (Microcrystalline cellulose) , Dose: a 250 mg capsule after breakfast for 6 weeks, Company: Tuba pharmaceutical company
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Yazd city girls high schools
Full name of responsible person
Samane Tefagh
Street address
Modarres street
City
Yazd
Province
Yazd
Postal code
8916785863
Phone
+98 35 3624 4595
Email
s.tefagh@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Afshin Zarghi
Street address
Shahid Beheshti University of Medical Science, Yaman Street
City
Tehran
Province
Tehran
Postal code
1985717443
Phone
+98 21 23871
Email
info@sbmu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahid Beheshti University of Medical Sciences
Proportion provided by this source
80
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

2

Sponsor
Name of organization / entity
Tuba pharmaceutical company
Full name of responsible person
Esmaeel Nazem
Street address
No.6, Shahid Fallahpoor street, Ferdowsi squar, Sepahbod Gharani Street,
City
Tehran
Province
Tehran
Postal code

۱۵۹۹۹۳۴۶۱۱
Phone
+98 21 8849 9794
Email
info@tuba18.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tuba pharmaceutical company
Proportion provided by this source
20
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
Other

Person responsible for general inquiries

Contact
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Samane Tefagh
Position
PhD student of Iranian traditional medicine
Latest degree
Medical doctor
Other areas of specialty/work
Traditional Medicine
Street address
Shams alley, across Tvanir, Vali-e-asr street
City
Tehran
Province
Tehran
Postal code
1516745811
Phone
+98 21 8877 3521
Fax
Email
s.tefagh@sbmu.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Samane Tefagh
Position
PhD student if Iranian traditional medicine
Latest degree
Medical doctor
Other areas of specialty/work
Traditional Medicine
Street address
Vali e asr
City
Tehran
Province
Tehran
Postal code
1998856349
Phone
+98 21 8877 3521
Fax
Email
s.tefagh@sbmu.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Samane Tefagh
Position
PhD student of Iranian traditional medicine
Latest degree
Medical doctor
Other areas of specialty/work
Traditional Medicine
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City
Tehran
Province
Tehran
Postal code
1516745811
Phone
+98 21 8877 3521
Fax
Email
s.tefagh@sbmu.ac.ir

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
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Not applicable
Title and more details about the data/document

Publishing the number and age of participants and clinical trial results before and after intervention which consist of cognitive function indicators and the level of sputum cortisol after making the data unidentifiable in the form of a Ph.D. thesis and an article indexing in ISI

When the data will become available and for how long

after PhD thesis defence

To whom data/document is available

researchers from academia and research institutes

Under which criteria data/document could be used

research studies

From where data/document is obtainable

Sending Email to the researcher, Samane Tefagh, at the email address: s.tefagh@sbmu.ac.ir

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

After receiving the applicant's email, the requested data will be sent back to the same email address within two weeks.

Comments