

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

06 Jul 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, with 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 Sciences, 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**

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**Province**

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**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**

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**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

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## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

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**Full name of responsible person**

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**Latest degree**

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**Other areas of specialty/work**

Traditional Medicine

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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

**Street address**

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**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**