

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 Jul 2026

### Boswellia resin extract effect on plasma levels of inflammatory cytokines in patients with Parkinson's disease

#### Protocol summary

##### Study aim

Investigation of anti-inflammatory effect of Boswellia resin extract on inflammatory factors in Parkinsons patients

##### Design

Two arm randomized trial, parallel groups, with control group, with blinding

##### Settings and conduct

This trial is performed in Imam Khomeini hospital complex based on block randomization in double blind manner. Every person who is involved in caring and treatment of patients including patient companions, physicians, nurses and investigators are blinded.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: UPDRS= mild and moderate stage, No family background of parkinson disease, BMI between 18-25, No peptic ulcer history, surgery or hemorrhage of gastrointestinal system, No NSAIDs or continuous systemic corticosteroid use for two previous months of research, No alcohol consumption, Age between 55 and 85, No record of other specific central nervous system disease like Alzheimer's disease, multifactorial dementia, medulla oblongata dementia, Huntington's disease, hydrocephalus, brain tumors, severe supra nuclear palsy, epilepsy, flocculation among brain tissue layers, or multiple sclerosis, Not taking drugs that might affect cognitive behaviour or perception like estrogen, deprenyl, vitamine E, neuroleptic compounds and anticholinergics, No consuming complements containing vitamine B12 or folic acid, No severe heart or vascular disease, No kidney or liver disorder  
Exclusion criteria: Acute viral, bacterial or severe infectious disease during research

##### Intervention groups

Boswellia resin extract group, Placebo group

##### Main outcome variables

Inflammatory blood factors

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20170315033086N4**

Registration date: **2019-04-12, 1398/01/23**

Registration timing: **retrospective**

Last update: **2019-04-12, 1398/01/23**

Update count: **0**

##### Registration date

2019-04-12, 1398/01/23

##### Registrant information

##### Name

Saeed Karima

##### Name of organization / entity

Shahid Beheshti University of Medical Sciences (SBMU)

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 9666 1028

##### Email address

karima@sbmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2017-06-22, 1396/04/01

##### Expected recruitment end date

2018-10-23, 1397/08/01

##### Actual recruitment start date

2017-10-02, 1396/07/10

##### Actual recruitment end date

2018-12-03, 1397/09/12

##### Trial completion date

2019-02-24, 1397/12/05

**Scientific title**

Boswellia resin extract effect on plasma levels of inflammatory cytokines in patients with Parkinson's disease

**Public title**

The effect of Boswellia resin extract on treatment of patients with Parkinson's disease

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

In accordance to UPDRS, only patients in mild and moderate stage will be recruited. No background of parkinson disease in patient's family. It must be recorded in the primary questionnaire. The substance consumed in this research make no conflict with prescribed medicines by the physician, and all the patients recruited in this study will receive the same combination of medicines. BMI between 18 to 25, this parameter is determined by researcher and physician. No background of peptic ulcer, any surgery of digesting system, or haemorrhage of digesting system. Age between 55 and 85. No severe heart or vascular disease. No kidney or liver disorder.

**Exclusion criteria:**

Acute or severe infectious disease (viral, bacterial) during research

**Age**

From **55 years** old to **85 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Care provider
- Investigator
- Outcome assessor

**Sample size**

Target sample size: **50**

Actual sample size reached: **50**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Randomization is designed based on four-sized block randomization. An unordered computer list is generated by an epidemiologist. Codes are written on envelopes and medication bottles. Patients allocation and sequencing are done blind.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

Patients allocation is done in a blinded manner. All staffs who are involved to perform the enrollment, physicians, nurses and investigator team are all masked.

**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, School of Medicine

**Street address**

Ground floor, medical faculty, Koodakyar Alley, Daneshjoo Blvd, Velenjak, Tehran, Iran

**City**

Tehran

**Province**

Tehran

**Postal code**

1985717434

**Approval date**

2016-06-05, 1395/03/16

**Ethics committee reference number**

IR.SBMU.MSP.REC.1395.603

**Health conditions studied****1****Description of health condition studied**

Parkinson disease

**ICD-10 code**

G20

**ICD-10 code description**

Parkinson disease

**Primary outcomes****1****Description**

Pro- and anti-inflammatory factors

**Timepoint**

At the recruitment day and after intervention

**Method of measurement**

ELISA assay kit

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Intervention group: Boswellia Resin extract receiving group, 3 times/day (400 mg)

**Category**

Treatment - Drugs

2

**Description**

Control group: Placebo group, 3 times/day (400 mg)

**Category**

Placebo

**Recruitment centers**

1

**Recruitment center**

**Name of recruitment center**

Imam Khomeini Complex Hospital

**Full name of responsible person**

Bahram Yaghmayi

**Street address**

Dr. Gharib St., Keshavarz Blv., Tehran, Iran

**City**

Tehran

**Province**

Tehran

**Postal code**

1419733141

**Phone**

+98 21 6658 2678

**Email**

Imamhospital@tums.ac.ir

**Sponsors / Funding sources**

1

**Sponsor**

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Bahram Yaghmayi

**Street address**

Velenjak St. , Shahid Chamran Highway, Tehran, Iran

**City**

Tehran

**Province**

Tehran

**Postal code**

1985717443

**Phone**

+98 21 2387 2570

**Email**

msp@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**

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**

Other

**Person responsible for general inquiries**

**Contact**

**Name of organization / entity**

Bahram Yaghmayi

**Full name of responsible person**

Shahid Beheshti University of Medical Sciences

**Position**

Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Biochemistry

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**Web page address**

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

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**Web page address**

## Person responsible for updating data

### Contact

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Bahram Yaghmayi

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**Web page address**

## 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

Not applicable

### 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

collected deidentified IPD, IPD collected for the primary outcome measure only

### When the data will become available and for how long

Deidentified data will be available starting from April, 2021

### To whom data/document is available

People working in academic institutions or people working in businesses.

### Under which criteria data/document could be used

No specific condition

### From where data/document is obtainable

Bahram Yaghmayi, Shahid Madani St., Tehran, Iran, Tel: +982123872570 Mob. 09215450282

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

The process is: 1- Asking a written request contain the main reasons of data importance for the applicant 2- After receiving the request letter, data will be provided in two weeks.

### Comments