Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 May 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
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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 pationts in mild and moderate stage will be recruited No background of parkinson desease 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
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1419733141
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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
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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
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Person responsible for updating data

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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