Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Evaluation of Silymarin therapeutic effect in multiple sclerosis patients receiving CinnoVex

Protocol summary

Study aim
Determination of Silymarin therapeutic effect in multiple Sclerosis patients receiving CinnoVex

Design
In this study, 60 patients with Multiple Sclerosis who have been admitted to Kashani Hospital in Isfahan are selected. Participants are randomly divided into intervention and control groups and each participant is assigned a code.

Settings and conduct
Patients referring to the Kashani hospital in Isfahan must be approved by the neurologist for the diagnosis of multiple sclerosis. Perform all stages of the test with patients satisfaction. These multiple sclerosis patients will be included in a randomized, double blind clinical trial.

Participants/Inclusion and exclusion criteria
Inclusion criteria: The study population is among people with multiple sclerosis who are in the Kashani medical center in Isfahan, who use Synovox drug for less than 1 year. Exclusion criteria: Patients with multiple sclerosis treated with other interferon beta drugs and immunosuppressive drugs, as well as patients who have already received sinoox and their treatment discontinued, are excluded.

Intervention groups
Intervention group: Patients with Multiple Sclerosis treated with CinnoVex and Silymarin Control group: Patients with multiple sclerosis treated with CinnoVex and placebo

Main outcome variables
Serum levels of interleukin 10, 17, 23, 35; Serum interferon-gamma; Serum beta-growth factor

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171220037977N1**
Registration date: **2018-01-07, 1396/10/17**
Registration timing: **prospective**

Last update: **2018-01-07, 1396/10/17**
Update count: **0**

Registration date
2018-01-07, 1396/10/17

Registrant information

Name
Vahid Shaygannejad

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 31 3667 6292

Email address
shaygannejad@med.mui.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-02-20, 1396/12/01

Expected recruitment end date
2018-04-20, 1397/01/31

Actual recruitment start date
2018-02-20, 1396/12/01

Actual recruitment end date
2018-04-20, 1397/01/31

Trial completion date
empty

Scientific title
Evaluation of Silymarin therapeutic effect in multiple sclerosis patients receiving CinnoVex

Public title
Silymarin in multiple Sclerosis

Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
People with multiple sclerosis who go to Kashani hospital in Isfahan. Patients taking CinnoVex for less than 1 year.
Exclusion criteria:
Patients with multiple sclerosis treated with other interferon beta drugs and immunosuppressive drugs
Patients who have already received CinnoVex and their treatment has been discontinued
Age
No age limit
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **60**
Actual sample size reached: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Random random, clustered using random numbers table
Blinding (investigator's opinion)
Double blinded
Blinding description
The pills are in the same boxes. Medication and placebo are coded while the physician and the pharmacy and patients do not know the codes.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Isfahan University of Medical Sciences
Street address
Isfahan University of Medical Sciences, Hezarjerib street, Isfahan, Iran
City
Isfahan
Province
Isfehan
Postal code
81746-73461
Approval date
2017-09-23, 1396/07/01
Ethics committee reference number
Ir.mui.rec.1395.1.012

Health conditions studied

1

Description of health condition studied
Therapeutic effect of silymarin
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Serum interleukin level 10
Timepoint
2 months before the intervention, 6 months after the intervention
Method of measurement
ELISA

2

Description
Serum interleukin level 17
Timepoint
2 months before the intervention, 6 months after the intervention
Method of measurement
ELISA

3

Description
Serum interleukin level 23
Timepoint
2 months before the intervention, 6 months after the intervention
Method of measurement
ELISA

4

Description
Serum interleukin level 35
Timepoint
2 months before the intervention, 6 months after the intervention
Method of measurement
ELISA

5

Description

Serum interferon gamma

Timepoint

2 months before the intervention, 6 months after the intervention

Method of measurement

ELISA

6

Description

Serum level of tumor growth factor beta

Timepoint

2 months before the intervention, 6 months after the intervention

Method of measurement

ELISA

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Silymarin tablets, 140 mg, 3 times a day, for 6 months, orally

Category

Treatment - Drugs

2

Description

Control group: Placebo tablets, 140 mg, 3 times a day, for 6 months, orally

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Kashani hospital

Full name of responsible person

Vahid Shaygannejad

Street address

Kashani hospital, Kashani street, Isfahan, Iran

City

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Email

Shaygannejad@med.mui.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Ahmad Movahedian Attar

Street address

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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

Esfahan University of Medical Sciences

Proportion provided by this source

100

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

Person responsible for general inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Vahid Shaygannejad

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Neurology

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Isfahan University of Medical Sciences, Hezarjerib street, Isfahan, Iran

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
Vahid Shaygannejad

Position
Professor

Latest degree
Specialist

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available