

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 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

Isfahan

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
Isfahan
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81746-73461
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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
Isfahan University of Medical Sciences, Hezarjerib street, Isfahan, Iran
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Phone
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Email
Shaygannejad@med.mui.ac.ir
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

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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