Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of silymarin on inflammatory factors TNF-α and IL-1β and it’s probable relationship with cognitive function of Alzheimer’s patients.

Protocol summary

Study aim
Determine the effectiveness of silymarin in improving Alzheimer's patients and using it as an adjunct

Design
(There is only one group with 20 members in the study and all participants receive one kind of intervention) Given that silymarin is currently available as a natural treatment for liver problems in the market, the study is in Phase 4.

Settings and conduct
In the Neurology Clinic of Imam Reza Hospital in Kermanshah, according to criteria of Alzheimer's patients are selected, The study compared the status of patients before receiving silymarin and after receiving silymarin. Patients' drug regimens do not change at the time of entry, and only silymarin is added to their drug regimen.The diet is supposed to give them three tablets of 140 mg of silymarin daily for three months. Before and after receiving silymarin, the measurement of inflammatory factors IL-1β and TNF-α , is performed by ELISA kit and the MMSE test for evaluation of cognitive function in patients.

Participants/Inclusion and exclusion criteria
Patients who diagnosed with brain imaging and biochemical tests, Alzheimer's by a neurologist. inclusion criteria: Patients diagnosed with brain imaging and biochemical tests, Alzheimer's have been approved by a neurologist. Non-entry criteria: Epilepsy, heart failure, kidney failure, dialysis, hypothyroidism, vitamin B12 deficiency, mental illness, stroke, brain tumor, hydrocephaly, brain infections, pregnancy, excerbation of symptoms when patiants want to start silymarin

Intervention groups
Because the study is for the first time, 20 patients with Alzheimer's disease are included in a pilot study, and the study is evaluated before receiving silymarin and after receiving silymarin.

Main outcome variables
Score of cognitive function in Mini Mental State Examination; Serum levels of TNF-α inflammatory factor; Serum levels of IL-1β inflammatory factor

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20131219015870N3**
Registration date: **2018-06-10, 1397/03/20**
Registration timing: **retrospective**

Last update: **2018-06-10, 1397/03/20**
Update count: **0**

Registration date
2018-06-10, 1397/03/20

Registrant information

Name
Amir Kiani

Name of organization / entity
Kermanshah University of Medical Science

Country
Iran (Islamic Republic of)

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+98 83 3427 6482

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-02-24, 1396/12/05

Expected recruitment end date
2018-05-26, 1397/03/05

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of silymarin on inflammatory factors TNF-α and IL-1β and it’s probable relationship with cognitive function of Alzheimer’s patients.

Public title

The effect of silymarin on Alzheimer’s diseases

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients who diagnosed with brain imaging and biochemical tests, Alzheimer's by a neurologist

Exclusion criteria:

epilepsy heart failure CKD hypothyroidism vitamon b 12 deficiency psychiatric desease stroke brain tumor hydrocephaly encephalitis pragnancy excerbation of symptoms when patiants want to start silymarin

Age

No age limit

Gender

Both

Phase

4

Groups that have been masked

No information

Sample size

Target sample size: **22**

Actual sample size reached: **20**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Patients' drug regimens do not change at the time of entry, and only silymarin is added to their medication regimen.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee in the research of Pharmaceutical Sciences Branch of Islamic Azad University

Street address

Pharmaceutical Sciences Branch of Islamic Azad University, Yakhchal ave,Gholhak

City

tehran

Province

Tehran

Postal code

193956466

Approval date

2017-02-01, 1395/11/13

Ethics committee reference number

IR.IAU.PS.REC.1395.56

Health conditions studied

1

Description of health condition studied

Alzheimer disease

ICD-10 code

G30

ICD-10 code description

Alzheimer's disease

Primary outcomes

1

Description

Score of cognitive function in Mini Mental State Examination

Timepoint

At the beginning of the study (before the intervention) and 3 months later

Method of measurement

Mini Mental State Examination

2

Description

Serum levels of TNF-α inflammatory factor

Timepoint

At the beginning of the study (before the intervention) and 3 months later

Method of measurement

ELISA

3

Description

Serum levels of IL-1β inflammatory factor

Timepoint

At the beginning of the study (before the intervention) and 3 months later

Method of measurement

ELISA

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: daily 3 tablets of 140 mg silymarin for 3 months
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam reza hospital
Full name of responsible person
Dr.Amir Kiani
Street address
Parastar Blvd, Imam reza hospital
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Faculty of Pharmaceutical Sciences, Islamic Azad University of Medical Sciences, Tehran
Full name of responsible person
Dr gholamreza amin
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Faculty of Pharmaceutical Sciences Islamic Azad University of Medical Sciences, Yakhchal Ave, Gholhak
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gh_amin@yahoo.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Faculty of Pharmaceutical Sciences, Islamic Azad University of Medical Sciences, Tehran
Proportion provided by this source
50
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
Persons

2

Sponsor
Name of organization / entity
Kermanshah University of Medical Sciences
Full name of responsible person
Dr daryoush afshari
Street address
Parastar Blvd, Imam reza hospital
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Kermanshah university of Medical Science
Proportion provided by this source
50
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
Persons

Person responsible for general inquiries

Contact
Name of organization / entity
Kermanshah University of Medical Sciences
Full name of responsible person
Dr amir kiani
Position
assistant professor
Latest degree

Ph.D.

Other areas of specialty/work
Toxicology

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Person responsible for scientific inquiries

Contact

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Ph.D.

Other areas of specialty/work
Toxicology

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Person responsible for updating data

Contact

Name of organization / entity
Faculty of Pharmaceutical Sciences, Islamic Azad University, Tehran Medical Branch

Full name of responsible person
Kiana Heydari

Position
Student of pharmacy

Latest degree
A Level or less

Other areas of specialty/work
Medical Pharmacy

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Faculty of Pharmaceutical Sciences, Islamic Azad University, Yakhchal Ave, Gholhak

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Tehran

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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
Yes - There is a plan to make this available

Analytic Code
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
The total potential data can be shared after unidentifiable people

When the data will become available and for how long
Start the access period one year after the print results

To whom data/document is available
Only for researchers working in academic and scientific institutions

Under which criteria data/document could be used
if The disclosure of requested information does not disturb other research related to this research

From where data/document is obtainable
By Dr. Amir Kiani's email Kermanshah University of Medical Sciences: akiani@kums.ac.ir

What processes are involved for a request to access data/document
The publisher send email to the principal responsible person, And the principal will respond to the publisher after checking, then this response will be passed from the publisher to the requesting person

Comments