

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The effect of silymarin on inflammatory factors TNF- $\alpha$ and IL-1 $\beta$ and its probable relationship with cognitive function of Alzheimer's patients.

#### Protocol summary

Examination; Serum levels of TNF- $\alpha$  inflammatory factor;  
Serum levels of IL-1 $\beta$  inflammatory factor

#### 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-1 $\beta$  and TNF- $\alpha$ , 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, exacerbation of symptoms when patients 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

#### 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)

##### Phone

+98 83 3427 6482

##### Email address

akiani@kums.ac.ir

##### 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- $\alpha$  and IL-1 $\beta$  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 vitamin b 12 deficiency psychiatric disease stroke brain tumor hydrocephaly encephalitis pregnancy exacerbation of symptoms when patients 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- $\alpha$  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-1 $\beta$  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

#### City

kermanshah

#### Province

Kermanshah

#### Postal code

6714415333

#### Phone

+98 83 3427 6301

#### Email

k2004heidary@gmail.com

## 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

#### Street address

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

#### City

Tehran

#### Province

Tehran

#### Postal code

193956466

#### Phone

+98 21 2264 0051

#### Email

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

#### City

Kermanshah

#### Province

Kermanshah

#### Postal code

6714415333

#### Phone

+98 83 3427 6301

#### Email

afshari\_d@yahoo.com

#### 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  
**Street address**  
Parastar blvd, Kermanshah University Medical Science  
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Kermanshah  
**Postal code**  
6734667149  
**Phone**  
+98 83 3427 6493  
**Email**  
akiani@kums.ac.ir

## Person responsible for scientific 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  
**Street address**  
Parastar Blvd, Kermanshah University of Medical Science  
**City**  
Kermanshah  
**Province**  
Kermanshah  
**Postal code**  
6734667149  
**Phone**  
+98 83 3427 6493  
**Email**  
akiani@kums.ac.ir

## 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  
**Street address**  
Faculty of Pharmaceutical Sciences, Islamic Azad University, Yakhchal Ave, Gholhak  
**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
193956466  
**Phone**  
+98 21 2264 0051  
**Email**  
k2004heidary@gmail.com

## 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