Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

the evaluation of effectiveness of oral silymarin on memory status of patients with dementia

Protocol summary

Summary

During a double blind placebo controlled clinical trial, from patients referred to neurology clinic of Emam Reza hospital in city of Kermanshah, 100 patients with a one year history of definite diagnosis of dementia, who fulfill criteria of the study will be enrolled and will be divided into intervention and control groups. After description of the study goals and receiving informed consent patients in the intervention group will receive 140 mg silymarin tablets (with trade name Livergol, Goldaru company) , three times a day and patients in control group will receive placebo tablets identical to silymarin tablets, three times a day for 12 weeks. Patient's memory state will be examined before and after 12 weeks intervention using mini mental state examination scale (MMSE scale). Any patient who meets the study exclusion criteria during the intervention will be excluded, and patient enrollment will be continued until reaching study sample size. At last data will be analyzed by statistical software to evaluate effectiveness oral silymarin.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201505091856N5**
Registration date: **2015-05-22, 1394/03/01**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2015-05-22, 1394/03/01

Registrant information

Name

Dariush Afshari

Name of organization / entity

Kermanshah University of Medical Sciences and Health Services

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Recruitment status

Recruitment complete

Funding source

kermanshah university of medical sciences

Expected recruitment start date

2015-05-09, 1394/02/19

Expected recruitment end date

2016-06-19, 1395/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

the evaluation of effectiveness of oral silymarin on memory status of patients with dementia

Public title

the evaluation of effectiveness of oral silymarin on memory status of patients with dementia

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion criteria: 1. definite diagnosis of dementia by an experienced neurologist 2. at least one year has past form the time of the diagnosis exclusion criteria: 1. illiterate persons 2. having epilepsy, cardiovascular diseases, metabolic diseases, respiratory diseases, orthopedic problems and renal failure with serum cratinin level more than 2 3. history of previous stroke 4. acute

and severe state of any disease including stroke, pulmonary infection, renal disease, metabolic disturbance or trauma leading to hospitalization during the study 5. using other self care programs that are effective on memory state of patents at the same time of study intervention

Age
No age limit

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Kermanshah University of Medical Sciences

Street address
Kermanshah University of Medical Sciences, Shahid Beheshti boulvered, Kermanshah

City
Kermanshah

Postal code

Approval date
2014-11-11, 1393/08/20

Ethics committee reference number
35213

Health conditions studied

1

Description of health condition studied
Dementia in Alzheimer disease

ICD-10 code
F00

ICD-10 code description
Alzheimer disease is a primary degenerative cerebral disease of unknown etiology with characteristic neuropathological and neurochemical features. The disorder is usually insidious in onset and develops slowly but steadily over a period of several years.

2

Description of health condition studied
Vascular dementia

ICD-10 code
F01

ICD-10 code description
Vascular dementia is the result of infarction of the brain due to vascular disease, including hypertensive cerebrovascular disease. The infarcts are usually small but cumulative in their effect. Onset is usually in later life.

3

Description of health condition studied
Dementia in other diseases classified elsewhere

ICD-10 code
F02

ICD-10 code description
Cases of dementia due, or presumed to be due, to causes other than Alzheimer disease or cerebrovascular disease. Onset may be at any time in life, though rarely in old age.

Primary outcomes

1

Description
memory status of patients

Timepoint
before and 12 weeks after intervention

Method of measurement
mini mental state examination scale

Secondary outcomes

1

Description
drug side effects

Timepoint
12 weeks after intervention

Method of measurement
history and physical examination

Intervention groups

1

Description
Silymarin, 140 mg tablets, 3 times a day (trade name, Livergol, goldaru company), for 12 weeks

Category
Treatment - Drugs

2

Description
Placebo tablets identical to silymarin tablets in shape and color, 3 times a day, for 12 weeks. Placebo tablets are made in pharmacology faculty of kermanshah university of medical sciences.

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
neurology clinic,Emam Reza Hospital of Kermanshah

Full name of responsible person
Dr Daryoush Afshari

Street address
Emam Reza Hospital, Parastar bulvard, Sorkhelijeh, Kermanshah

City
Kermanshah

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice-chancellor for research, Kermanshah University of Medical Sciences

Full name of responsible person
Mr. Shirzadian

Street address
Kermanshah University of Medical Sciences, building no.2, Shahid Beheshti boulvered, Kermanshah

City
Kermanshah

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Vice-chancellor for research, Kermanshah University of Medical Sciences

Proportion provided by this source
100

Public or private sector
empty

Domestic or foreign origin
empty

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
empty

Person responsible for general inquiries

Contact

Name of organization / entity
Kermanshah University of Medical Sciences

Full name of responsible person
Dr. Daryoush Afshari

Position
neurologist/ Associate Professor

Other areas of specialty/work

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Person responsible for updating data

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MD, resident of Neurology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty