

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 2026

Evaluating the Antioxidative Effect of Silymarin on CAPD Patients

Protocol summary

Summary

The purpose of our study was to investigate the effect of silymarin on oxidative agents such as isoprostane, antioxidant factors like catalase and total capacity antioxidant. this study is randomized , double-blind , controlled placebo trial. The inclusion criteria is age between 18 to 60 years and exclusion criteria are peritonitis in 2 months , hepatitis , using antioxidants drugs such as vitamin C , taking hormones , levothyroxine , and smoking. Number of samples is 60 (35 in treatment group, 25 in placebo group) and after 2 months of treatment with a dose of 140 mg every 8 hours, the tests before and after medication was measured then was compared. we expected to see a reduction antioxidant agents and increase in antioxidant enzymes with the use of this drug and also by reducing inflammation leads to improvement of anemia, osteoporosis in short term period and prevention of cancer in long term.

General information

Acronym

CAPD

IRCT registration information

IRCT registration number: **IRCT2013110315256N1**

Registration date: **2013-12-09, 1392/09/18**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-12-09, 1392/09/18

Registrant information

Name

Soraya Khajehrezae

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 64 1525 4526

Email address

khajerezae@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Medical and Natural Products Chemistry Research
Center- Shiraz University Of Medical Sciences

Expected recruitment start date

2013-09-23, 1392/07/01

Expected recruitment end date

2013-12-21, 1392/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the Antioxidative Effect of Silymarin on CAPD
Patients

Public title

Evaluating the Effect of Silymarin on CAPD Patients

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criterion: patients undergo Peritoneal Dialysis and are on the follow up of nephrologist at Emam reza Clinic between 18-60 years old. Exclusion criteria: patients undergo Peritoneal Dialysis who had peritonitis in recent 2 month; hepatitis; or using other antioxidant, anti pregnancy, levothyroxin drugs and smoking.

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 60

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

Ethics committee of shiraz university of medical sciences

Street address

medicine department, bulding No2, 9th floor, medical ethics group

City

shiraz

Postal code

Approval date

2012-07-30, 1391/05/09

Ethics committee reference number

ct-p-91-3818

Health conditions studied

1

Description of health condition studied

Renal failure, peritoneal dialysis

ICD-10 code

N17-N19

ICD-10 code description

Renal failure

Primary outcomes

1

Description

glutathione peroxidase antioxidant enzyme in RBC

Timepoint

2 month (before and after drug)

Method of measurement

serlogic blood test

2

Description

antioxidant catalase enzyme

Timepoint

2 month (before and after drug)

Method of measurement

serlogic blood test

3

Description

antioxidant isoprostane enzye F2a

Timepoint

2 month (before and after drug)

Method of measurement

serlogic blood test

4

Description

antioxidant capacity FRAP

Timepoint

2 month (before and after drug)

Method of measurement

serlogic blood test

Secondary outcomes

empty

Intervention groups

1

Description

Receiving silymarin drug 140mg every 8 hours for 2 month

Category

Treatment - Drugs

2

Description

in control group we used similar tablet in shape , color to Silymarin drug, which is consisted of starch as placebo and they should take each hours for 2 month.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

medical and natural products chemistry research center

Full name of responsible person

Soraya Khajeh Rezae

Street address

Zand street

City

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr. Roozbeh

Street address

Zand ave.

City

Shiraz

Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Soraya Khajeh Rezae

Position

MD

Other areas of specialty/work
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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