Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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)

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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 commitee 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 dyalisis
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

Shiraz

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 Universitty of Medical Sciences
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Soraya Khajeh Rezae
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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