

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 2026

The study of Livergol® effect on serum levels of tumor necrosis factor- α , malondialdehyde, interleukin-1, paraoxonase-1, catalase and neopterin in rheumatoid arthritis patients

Protocol summary

Summary

50 patients with Rheumatoid Arthritis diagnosed by a Rheumatologist and patient are free to participate in this study, they are received daily 3 tablets of 140 mg livergol® for 3 months as adjuvant addition regimen routinely receive. During this study ,before and after intervention, blood sample was collected from patients. blood samples will be analyzed in the following way: Evaluating the changes of TNF- α and interleukin-1 by ELISA kits systems. Evaluating the changes of Neopetrine and Malondialdehyde by HPLC system. Evaluating the changes of catalase, and paraoxonase by spectrophotometry system. The data were analyzed by spss16 software.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013121915870N1**

Registration date: **2015-05-23, 1394/03/02**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-05-23, 1394/03/02

Registrant information

Name

Amir Kiani

Name of organization / entity

Kermanshah University of Medical Science

Country

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Phone

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Email address

akiani@kums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research of Kermanshah University of Medical Sciences

Expected recruitment start date

2014-09-07, 1393/06/16

Expected recruitment end date

2014-12-07, 1393/09/16

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The study of Livergol® effect on serum levels of tumor necrosis factor- α , malondialdehyde, interleukin-1, paraoxonase-1, catalase and neopterin in rheumatoid arthritis patients

Public title

The study of Livergol® effect on rheumatoid arthritis patients

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria: having four of the seven criteria, of American College of Rheumatology for six weeks and Diagnosis by a Rheumatologist Exclusion criteria: Patients participating in the study will be free to withdraw from the study.

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 50

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

In this study the Matrix Metalloproteinase 2,9(MMP2 ,MMP9) and vascular endothelial growth factor(VEGF) were measured.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Kermanshah University of Medical Science

Street address

Shahid Beheshti Bolva, Kermanshah, Iran

City

Kermanshah

Postal code

6714869914

Approval date

2014-09-06, 1393/06/15

Ethics committee reference number

23322

Health conditions studied

1

Description of health condition studied

rheumatoid arthritis

ICD-10 code

M05

ICD-10 code description

Seropositive rheumatoid arthritis

Primary outcomes

1

Description

interleukin 1

Timepoint

before and after advising the drug

Method of measurement

ELISA

2

Description

TNF-a

Timepoint

before and after advising the drug

Method of measurement

ELISA

3

Description

neopterin

Timepoint

before and after advising the drug

Method of measurement

HPLC

4

Description

Malondialdehyde

Timepoint

before and after advising the drug

Method of measurement

HPLC

5

Description

catalase

Timepoint

before and after advising the drug

Method of measurement

spectrophotometry system

6

Description

paraoxonase

Timepoint

before and after advising the drug

Method of measurement

spectrophotometry system

Secondary outcomes

1

Description

ESR

Timepoint

before and after the drug

Method of measurement

westregreen

2

Description

CRP

Timepoint

before and after the drug

Method of measurement

ELISA

3

Description

mmp-2

Timepoint

before and after the drug

Method of measurement

ELISA and gelatin zymography

4

Description

mmp-9

Timepoint

before and after the drug

Method of measurement

ELISA and gelatin zymography

Intervention groups

1

Description

daily 3 tablets of 140 mg livergol® for 3 months

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

School of Medicine, Kermanshah University of Science

Full name of responsible person

Dr.Amir Kiani

Street address

School of Medicine, Kermanshah University of Science

City

Kermanshah

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of Kermanshah University of Medical Sciences

Full name of responsible person

Dr.Farid najafi

Street address

Vice Chancellery of Research & Technology Affairs,

shahid beheshti blv, 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 of 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.Amir Kiani

Position

PHD of toxicology

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity
School of Pharmacy, Kermanshah University of
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Phone

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