

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

31 May 2026

### The study of Livergol® effect on serum levels of tumor necrosis factor- $\alpha$ , 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- $\alpha$  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

Iran (Islamic Republic of)

##### Phone

+98 83 3427 6482

##### 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-  $\alpha$ , 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

#### Street address

School of Medicine, Kermanshah University of Medical Sciences , Kermanshah

#### City

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#### Postal code

#### Phone

+91 88316929

#### Fax

#### Email

amir1kiani@yahoo.com

#### Web page address

## Person responsible for scientific 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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mehrddad.shavandi@gmail.com  
**Web page address**

## Person responsible for updating data

### Contact

**Name of organization / entity**  
School of Pharmacy, Kermanshah University of  
Medical Science  
**Full name of responsible person**  
Mehrddad Shavandi  
**Position**  
Student of Pharmacy  
**Other areas of specialty/work**  
**Street address**  
**City**  
**Postal code**  
**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*