

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The effect of calcitriol on progress and activity of Lupus nephritis

Protocol summary

ghavidelparsa@gums.ac.ir

Summary

The investigators plan to conduct randomised, double-blind placebo controlled trial to study effects of calcitriol on progress and activity of glomerulonephritis due to Systemic Lupus Erythematosus. Fifty patients with clinically quiescent Systemic Lupus Erythematosus and biopsy-proven glomerulonephritis will be recruited and randomly assigned to treatment group or control group. Patients in treatment group will receive calcitriol at a fixed dose of 0.25 µg (one oral pearl) daily and Patients in control group will receive placebo similar to intervention 1 oral unit daily for 1 year. Renal function based on the American college of rheumatology renal response criteria, Glomerular Filtration Rate, Proteinuria, Systemic Lupus Erythematosus Disease Activity Index and serum inflammatory markers will be monitored.

Recruitment status

Recruitment complete

Funding source

Vice- Chancellorship for Research, Guilan University of Medical Sciences, Iran

Expected recruitment start date

2013-04-21, 1392/02/01

Expected recruitment end date

2013-10-23, 1392/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013030912762N1**

Registration date: **2013-04-20, 1392/01/31**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2013-04-20, 1392/01/31

Registrant information

Name

Banafsheh Ghavidel parsa

Name of organization / entity

Guilan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 912 327 7268

Email address

Scientific title

The effect of calcitriol on progress and activity of Lupus nephritis

Public title

Therapeutic effect of vitamin D on renal manifestation of systemic lupus erythematosus

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: aged 18-65 years; baseline SLEDAI score ≤ 4 ; estimated glomerular filtration rate more than 15 ml/min/1.73m²; proteinuria > 1 g/day (or proteinuria > 1 g/g-Cr) in 2 consecutive samples within 12 weeks despite ACE inhibitor at least 3 months; on maintenance dose of prednisolone < 15 mg/day, with or without other immunosuppressive medications; serum calcium level in normal range(8.5-10.5 mg/dl); history of biopsy-proven lupus nephritis clinical quiescent SLE for at least 3 month; willingness to give written consent and comply with the study protocol; Exclusion Criteria: Pregnancy, lactating or childbearing potential without effective method of birth control; Severe gastrointestinal disorders that interfere with their ability to receive or

absorb oral medication; History of malignancy, including leukemia and lymphoma within the past 2 years; Systemic infection requiring therapy at study entry; Any other severe coexisting disease such as, but not limited to, chronic liver disease, myocardial infarction, cerebrovascular accident, malignant hypertension; History of drug or alcohol abuse within past 2 years; Vitamin D deficiency(25 hydroxy vitamin D less than 20ng/ml); Participation in any previous trial on vitamin D analogue; Patients receiving treatment of vitamin D and/or its analogue for other medical reasons within the past 4 weeks; Patients who are taking multivitamin supplement that contains vitamin D could be enrolled after 4 weeks of wash out period by changing to a preparation that has no vitamin D; On other investigational drugs within last 30 days; History of a psychological illness or condition such as to interfere with the patient's ability to understand the requirement of the study; History of non-compliance; Known history of sensitivity or allergy to vitamin D analogs

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **50**

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**

Vice- Chancellorship for Research, Guilan University of Medical Sciences, Iran

Street address

Research Deputy Building of Guilan University of Medical Sciences, Emam Khomeini boulevard, Rasht, Iran.

City

Rasht

Postal code**Approval date**

2013-01-01, 1391/10/12

Ethics committee reference number

1910354604

Health conditions studied**1****Description of health condition studied**

Systemic lupus erythematosus

ICD-10 code

M32.1

ICD-10 code description

Systemic lupus erythematosus with organ or system involvement

Primary outcomes**1****Description**

proteinuria

Timepoint

every 2 month

Method of measurement

U/A

2**Description**

GFR

Timepoint

every 2 month

Method of measurement

U/A

Secondary outcomes**1****Description**

renal function

Timepoint

after 1 year

Method of measurement

based on on the ACR renal response criteria

2**Description**

activity of lupus

Timepoint

after 1 year

Method of measurement

SLEDAI

3**Description**

serum inflammatory markers

Timepoint

after 1 year

Method of measurement

routin laboratory test

Intervention groups**1****Description**

Patients will receive calcitriol at a fixed dose of 0.25 µg (one oral pearl) daily.

Category

Treatment - Drugs

2**Description**

Patients will receive placebo similar to intervention 1 oral unit daily.

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Razi hospital

Full name of responsible person**Street address**

Razi Hospital, Sardargangal St. , Rasht, Iran

City

Rasht

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Vice- Chancellorship for Research, Guilan University of Medical Sciences, Iran

Full name of responsible person

Dr Tabari

Street address

Research Deputy Building of Guilan University of Medical Sciences, Emam Khomeini boulevard, Rasht, Iran.

City

Rasht

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

Yes

Title of funding source

Vice- Chancellorship for Research, Guilan University of Medical Sciences, Iran

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**

Student Research Committee, Guilan University of Medical Sciences, Iran

Full name of responsible person

Alireza Amir Maafi

Position

Medical student/ Minister of Student Research Committe

Other areas of specialty/work**Street address**

Student Research Committee Office, Research Deputy Building of Guilan University of Medical Sciences, Emam Khomeini boulevard, Rasht, Iran.

City

Rasht

Postal code**Phone**

+98 18 1425 4702

Fax

+98 13 1322 8842

Email

alireza.am427@gmail.com

Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Guilan University of Medical Sciences, Iran

Full name of responsible person

Banafsheh Ghavidel Parsa

Position

Asistant professor of Rheumatology

Other areas of specialty/work**Street address**

Rheumatology Department, Razi Hospital, Sardargangal St. , Rasht, Iran

City

Rasht

Postal code**Phone**

+98 18 1425 4702

Fax**Email**

bghavidelparsa@gmail.com

Web page address**Person responsible for updating data****Contact**

Name of organization / entity

Student Research Committee. Guilan University of
Medical Sciences, Iran

Full name of responsible person

Alireza Amir Maafi

Position

Medical student/Minister of Student Research
Committee

Other areas of specialty/work**Street address**

Student Research Committee Office, Research Deputy
Building of Guilan University of Medical Sciences,
Emam Khomeini boulevard, Rasht, Iran.

City

Rasht

Postal code**Phone**

00

Fax**Email**

alireza.am427@gmail.com

Web page address**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