Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

The effect of calcitriol on progress and activity of Lupus nephritis

Protocol summary

Summary

The investigators plan to conduct randomised, double-blind placebo controlled trial to study effects of calcitriol on progress and activity of glumerulonephritis due to Systemic Lupus Erythematosus. Fifty patients with clinically quiescent Systemic Lupus Erythematosus and biopsy-proven glumerulonephritis 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, Glomular Filtration Rate, Proteinuria, Systemic Lupus Erythematosus Disease Activity Index and serum inflammatory markers will be monitored.

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

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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

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
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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
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City
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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

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Person responsible for updating data

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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