Clinical Trial Protocol
Iranian Registry of Clinical Trials

25 Jun 2026

Evaluation of serum level of 25-hydroxy vitamin-D on Multiple Sclerosis attack under treatment with methyl prednisolone pulse on Sina Hospital

Protocol summary

Summary

We collect 10 milileters blood from patients for evaluation serum level of vitamin D3 and evaluate patients by Expanded Disability Status Scale (EDSS). Then patients in attack will receive pulse therapy for 5 days with methylprednisolone.After 8 weeks we check EDSS again.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201305281859N7**
Registration date: **2015-10-17, 1394/07/25**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2015-10-17, 1394/07/25

Registrant information

Name

Mohammad Ali Sahraian

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 6634 8571

Email address

msahrai@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research ,Tehran University of Medical Sciences

Expected recruitment start date

2013-06-21, 1392/03/31

Expected recruitment end date

2015-06-21, 1394/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of serum level of 25-hydroxy vitamin-D on Multiple Sclerosis attack under treatment with methyl prednisolone pulse on Sina Hospital

Public title

Relationship between serum level of vitamin-D3 and Expanded Disability Status Scale (EDSS) changes before and 8 weeks after methylprednisolone pulse therapy in multiple sclerosis (MS) patients

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: 1- Patients with multiple sclerosis based on McDonalds Criteria. 2- Patients type relapsing-remitting (RRMS). 3-EDSS less than 5 before attack. 4-Less than 5 years after MS diagnosis. 5-Less than 5 attacks in the duration of MS diagnosis. Exclusion criteria: 1- Association with any diseases such as liver diseases, renal diseases, bone marrow disfunction, sarcoidosis, renal stone,hypercalcemia. 2-pregnancy or breast feeding. 3-Using drugs such as hydrochlorothiazide, phenytoin, barbiturate, digital.

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features
The patients with serum level of vitamin D3 less than 30 nanogram per milliliter (ng/ml) will divided in to two groups with and without treatment by single dose injection of vitamin-D3 based on random numbers table. The patients with serum level of vitamin-D3 more than 30nanogram per milliliter (ng/ml) will not receive any treatment with vitamin-D3.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Tehran University of Medical Sciences Ethics Committee

Street address
Vice chancellor for research ,Tehran University of Medical Sciences, Qods St, Keshavarz Blvd.

City
Tehran

Postal code

Approval date
2015-09-23, 1394/07/01

Ethics committee reference number
IR.TUMS.REC.1394.823

Health conditions studied

1

Description of health condition studied
Multiple Sclerosis

ICD-10 code
G35

ICD-10 code description
Disseminated Multiple Sclerosis

Primary outcomes

1

Description
The rate of recovery after attack

Timepoint
Before intervention and two months after intervention

Method of measurement
Physical examination done by neurologist and using Expanded Disability Status Scale (EDSS)

Secondary outcomes

1

Description
Expanded Disability Status Scale (EDSS)

Timepoint
Before intervention and two months after intervention

Method of measurement
Physical examination done by neurologist based on revised Mc-Donald (2010)

2

Description
serum level of 25-hydroxy vitamin-D3

Timepoint
Before intervention and two months after intervention

Method of measurement
Blood test

Intervention groups

1

Description
Amp vitamin-D3 ,chemical formulation active vitamin-D3 (calciteriol) , 300000 IU / day and single dose, intramuscular, made in Osva Pharmaceutical company in Islamic Republic Of Iran, not having generic name.

Category
Treatment - Drugs

2

Description
In 20 patients with low levels of vitamin D 3 whom are selected based on random numbers table , on the last day of 5 days pulse therapy , vitamin D 3 ampule will not be injected. They will be examined based on EDSS changes 8 weeks after pulse therapy.

Category
Treatment - Drugs

3

Description
In 20 patients with sufficient levels of vitamin D 3, therapy will not be given. They will be examined based on EDSS changes 8 weeks after pulse therapy.

Category
Treatment - Drugs

4

Description

In 20 patients with low levels of vitamin D 3 whom are selected based on random numbers table , on the last day of 5 days pulse therapy , vitamin D 3 ampule will be injected. They will be examined based on EDSS changes 8 weeks after pulse therapy.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Sina Hospital

Full name of responsible person

Dr. Mohammad Ali Sahraian

Street address

Sina Hospital, before Hasan abad Square , Imam Khomeini Street.

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research ,Tehran University of Medical Sciences

Full name of responsible person

Dr. Masoud Yunesian

Street address

Vice chancellor for research ,Tehran University of Medical Sciences, Qods St, Keshavarz Blvd.

City

Tehran

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 ,Tehran 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

Sina Hospital

Full name of responsible person

Dr. Shadi Assefi

Position

MD, Resident of neurology

Other areas of specialty/work

Street address

Sina Hospital, Hasan Abad Sq., Imam Khomeini St.

City

Tehran

Postal code

1136746911

Phone

+98 21 6634 8571

Fax

Email

sh.assefi@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Sina Hospital

Full name of responsible person

Dr Mohammad Ali Sahraian

Position

Neurologist- MS Fellowship/Associate Professor

Other areas of specialty/work

Street address

Sina Hospital, Hasan Abad Sq., Imam Khomeini St.

City

Tehran

Postal code

1136746911

Phone

+98 21 6634 8571

Fax

Email

msahrai@sina.tums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Sina Hospital

Full name of responsible person

Dr. Rozita Doosti

Position

General Physician/Researcher

Other areas of specialty/work

Street address

Sina Hospital, Hasan Abad Sq., Imam Khomeini St.

City

Tehran

Postal code

1136746911

Phone

+98 21 6634 8571

Fax

Email
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