

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

16 Sep 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

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##### 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.

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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.

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##### Postal code

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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*