

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

18 Jun 2026

### Clinical trial of the effect of Thyroid hormones in comparison to placebo on Magnetization Transfer Ratio in Gadolinium enhancing lesions in magnetic resonance imaging of patients with Multiple Sclerosis

#### Protocol summary

##### Summary

Multiple sclerosis (MS) is a chronic inflammatory disease which involves central nervous system and causes demyelination. Complete remyelination happens as a result of oligodendrocyte precursor cells activity in the acute phase of MS. However, as the disease turns chronic, remyelination fails idiopathically. Because of limited regeneration ability of nervous system, present treatments do not change the disease course largely. So recently treatment methods which involve self-regeneration and/or neuron protection have been suggested. The goal of this project is to assess the role of Liothyronine Sodium as an enhancing self-regeneration medication next to acute demyelination. The study is designed as a double-blind randomized clinical trial on 70 relapsing-remitting MS patients admitting at hospital for corticosteroid therapy in their relapse phase, with Liothyronine Sodium/Placebo administered as a supplement to their routine medication for 3 months from their admission date. Patients will undergo a detailed physical examination, a neuropsychological battery, thyroid function tests and Magnetic Resonance Imaging both at the beginning and in the end of the study. The primary outcome of this study is the effect of Liothyronine Sodium on the Magnetization Transfer Ratio (MTR) of Gadolinium-enhancing lesions of the brain as a measure of remyelination.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201210051859N6**

Registration date: **2013-01-27, 1391/11/08**

Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2013-01-27, 1391/11/08

##### 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

Tehran University of Medical Sciences ,Vice Chancellor of Research

##### Expected recruitment start date

2013-02-05, 1391/11/17

##### Expected recruitment end date

2015-03-05, 1393/12/14

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Clinical trial of the effect of Thyroid hormones in comparison to placebo on Magnetization Transfer Ratio in Gadolinium enhancing lesions in magnetic resonance imaging of patients with Multiple Sclerosis

##### Public title

Effect of Thyroid hormones on imaging findings of patients with multiple sclerosis

## Purpose

Treatment

## Inclusion/Exclusion criteria

Inclusion criteria: 1) Definite diagnosis of relapsing-remitting Multiple Sclerosis according to McDonald criteria revised in 2010 (Polman, Reingold et al. 2011). 2) Admission during the relapse phase (in the first 2 weeks from the onset of symptoms) Relapse definition: appearance of a new sign or exacerbation of a present sign which lasts for at least 24 hours without infection or any other possible reason. (Signs consist of Hemiparesis, paraparesis, hemiataxia, myelopathy, any sensation disorder.) 3) 5 days IV Methylprednisolone therapy for relapse. 4) Expanded Disability Scale Status (before relapse) equal or less than 5.5. 5) Age between 23 and 55 years old. 6) Minimum disease duration of 5 years. Exclusion criteria: 1) Thyroid function tests impairment (Thyroid Stimulating Hormone level less than 1  $\mu$ U/mL). 2) Administration of other drugs containing thyroid hormones during /prior to the study. 3) Prior administration of cytotoxic/immunosuppressive medications (e.g. mitoxantrone, azathioprine, cellcept) 4) Existence of any medical condition which is a contraindication for administering thyroid hormones: history of arrhythmia, myocardial infarction or congestive heart disease, heart failure, resting pulse rate more than 90/min, history of autoimmune thyroid disease, thyroid adenoma, hyperthyroidism, adrenal cortical insufficiency, diabetes, pregnancy, breast feeding, and women in reproductive age who do not use a safe birth control method. 5) History of central nervous system disorders other than multiple sclerosis, psychiatric, metabolic, rheumatologic and autoimmune disorders, and drug or alcohol abuse during the last month before study. 6) History of brain damage, cancer, chronic liver, kidney, heart or endocrine disease and vitamin D metabolic disorders. 7) Medications interfering absorption or metabolism of thyroid hormones such as oral contraceptives and Cholestyramine. 8) Medications which absorption or metabolism is affected by thyroid hormones, such as Tricyclic antidepressants and anticoagulants. 9) Abnormal rhythm or repolarization phase disorders in Electrocardiogram. 10) Disability to take Magnetic resonance imaging. 11) Disability to read or understand the informed consent. 12) Participation in any other clinical trial during the past 3 months.

## Age

From **23 years** old to **54 years** old

## Gender

Both

## Phase

1-2

## Groups that have been masked

*No information*

## Sample size

Target sample size: **70**

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Double blinded

## Blinding description

## Placebo

Used

## Assignment

Parallel

## Other design features

Randomization: Stratified Block randomization Since some of the data which will be used to measure primary or secondary outcomes is gathered by physical examination, the study has been designed as a double-blind clinical trial. Knowing in which group the patient is may affect examiners' clinical judgment.

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Tehran University of Medical Sciences

##### Street address

Qods St., Keshavarz Blvd.

##### City

Tehran

##### Postal code

141555799

#### Approval date

2012-09-22, 1391/07/01

#### Ethics committee reference number

16697-64465

## Health conditions studied

### 1

#### Description of health condition studied

Multiple Sclerosis

#### ICD-10 code

G35

#### ICD-10 code description

Multiple sclerosis (of): NOS brain stem cord disseminated generalized

## Primary outcomes

### 1

#### Description

Voxel-wise Magnetization Transfer Ratio changes in Gadolinium enhancing lesions

#### Timepoint

before intervention, 3 months after initiation

#### Method of measurement

Magnetic Resonance Imaging with contrast

## Secondary outcomes

### 1

#### Description

Voxel-wise Magnetization Transfer Ratio changes in normal appearing white matter

#### Timepoint

before intervention,3 months after initiation

#### Method of measurement

Magnetic Resonance Imaging

### 2

#### Description

Expanded Disability Status Scale (EDSS)

#### Timepoint

before intervention,3 months after initiation

#### Method of measurement

physical examination

### 3

#### Description

symbol digit modalities test (SDMT)

#### Timepoint

before intervention,3 months after initiation

#### Method of measurement

physical examination

### 4

#### Description

voxel-wise Magnetization Transfer Ratio changes in Gadolinium non-enhancing lesions

#### Timepoint

before intervention,3 months after initiation

#### Method of measurement

Magnetic Resonance Imaging

## Intervention groups

### 1

#### Description

Intervention 2: control group placebo, tablet first week 1 tablet daily, next 11 weeks 2 tablets daily, last week 1 tablet daily

#### Category

Treatment - Drugs

### 2

#### Description

Intervention 1: intervention group tablet Liothyronine Sodium 25 microgram, Iran Hormone company, Iran first week 1 tablet daily, next 11 weeks 2 tablets daily, last week 1 tablet daily

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Sina Hospital Multiple Sclerosis research center

##### Full name of responsible person

Dr. Mohammad Ali Sahraian

##### Street address

Sina Hospital Multiple Sclerosis research center, Imam Khomeini St.

##### City

Tehran

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Tehran University Of Medical Sciences,vice chancellor for research

##### Full name of responsible person

Dr. Akbar Fotouhi

##### Street address

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

Tehran University Of Medical Sciences,vice chancellor for research

#### 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

Tehran University Of Medical Sciences

##### Full name of responsible person

Shokufeh Sadaghiani

##### Position

Medical student

##### Other areas of specialty/work

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**Full name of responsible person**

Mohammad Ali Sahraian

**Position**

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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*