

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Aug 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

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Name of organization / entity

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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 µIU/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

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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

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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