Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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.
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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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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

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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