Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Comparison of the effectiveness of Trazodone with placebo in preventing acute sleep disturbances caused by corticosteroid pulse in hospitalized patients with MS

Protocol summary

Study aim

Comparison of the effectiveness of trazodone with placebo in preventing acute sleep disturbances caused by corticosteroid pulse in hospitalized patients with MS

Design

This study is a randomized double-blind placebo control clinical trial that will perform on 48 patients with relapsing forms of MS between the ages of 18 and 65 years who have been hospitalized to the neurology department of Sina Hospital in order to receive corticosteroid pulse.

Settings and conduct

In this study, the effect of trazodone will be investigated on MS patients who are candidates for corticosteroid pulse and are hospitalized in the neurology department of Sina Hospital. For all patients, demographic information, underlying condition, and medications are recorded at the beginning. The patient is then given 50 mg of Trazodone or placebo every night from the first day of hospitalization until the day of discharge at 9 o'clock. The Verran and Snyder-Halpern questionnaire (VSH) is filled for all patients at the beginning of hospitalization and every morning based on the patient overnight sleep.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with relapsing-remitting MS who are between 18 and 65 years old and hospitalized for treatment with corticosteroid pulse. Hospitalized patients who are candidates for corticosteroid pulse at the rate of 1 gram per day for 3 to 5 days. Excluison criteria: Receiving medicine that affect sleep during the past 2 weeks; Having primary insomnia; History of hypersensitivity reaction to Trazodone; Severe chronic renal or liver failure; Pregnancy and lactation

Intervention groups

Patients in the intervention group receive Trazodone 50 mg tablets of Tehran Shimi Company and in the control group receive placebo tablets from the first day of hospitalization until the day of discharge every night at 9 o'clock.

Main outcome variables

Insomnia score in VSH questionnaire

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210707051810N1**
Registration date: **2021-09-01, 1400/06/10**
Registration timing: **registered_while_recruiting**

Last update: **2021-09-01, 1400/06/10**
Update count: **0**

Registration date

2021-09-01, 1400/06/10

Registrant information

Name

Maryam Sharif

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8601 7570

Email address

maryamsharif.424@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-09-01, 1400/06/10

Expected recruitment end date

2022-02-09, 1400/11/20

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the effectiveness of Trazodone with placebo in preventing acute sleep disturbances caused by corticosteroid pulse in hospitalized patients with MS

Public title
Evaluation of the effect of Trazodone in hospitalized patients with MS
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with relapsing-remitting MS who are between 18 and 65 years old and hospitalized for treatment with corticosteroid pulse. Hospitalized patients who are candidates for corticosteroid pulse at the rate of 1 gram per day for 3 to 5 days.
Exclusion criteria:
Receiving other sleeping pills such as Barbiturates, Benzodiazepines, Doxepin, Melatonin and Zolpidem in the last 2 weeks Having Primary Insomnia Trazodone use in the last 2 weeks Taking Monoamine oxidase inhibitor drugs in the last 2 weeks History of hypersensitivity reaction to Trazodone or any components in the formulation Severe chronic renal failure (Creatinine clearance less than 30 ml/min) and liver failure Pregnancy and lactation Patients receiving concomitant Intravenous immunoglobulin or plasma exchange other than Corticosteroid pulse
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **48**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization with quadruple blocks based on a table of random numbers
Blinding (investigator's opinion)
Double blinded
Blinding description
The patient, the treating physician, and the person monitoring the patient are blind to the intervention. The study is double blind. The main researcher in the study encodes the drugs in groups a and b, and he is aware of the drug and the placebo of the cans, but is blind about which patient receives which drug package code. The researcher who gives patients medication and perform evaluation tests, the data analyzer, and also the patients are blind to the study groups. It most be considered that the drug and placebo are completely similar in appearance.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committee of Tehran University of Medical Sciences
Street address
16 Azar Street
City
Tehran
Province
Tehran
Postal code
14176141141
Approval date
2021-06-01, 1400/03/11
Ethics committee reference number
IR.TUMS.TIPS.REC.1400.040

Health conditions studied

1

Description of health condition studied
MS
ICD-10 code
G35
ICD-10 code description
Multiple sclerosis

Primary outcomes

1

Description
Insomnia score in Verran and Snyder-Halpern questionnaire (VSH)
Timepoint
Every day from the first day of hospitalization until the day of discharge (A total of 3 to 5 days)
Method of measurement
VSH questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Patients in this group use 50 mg trazodone tablets of Tehran Shimi Company every night at 9 o'clock from the first day of hospitalization until the day of discharge.
Category
Prevention

2

Description
Control group: Patients in the control group receive a placebo product made by Tehran Shimi Company every night at 9 o'clock from the first day of hospitalization until the day of discharge.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Sina hospital
Full name of responsible person
Hooshyar Honarmand
Street address
Sina Hospital, Imam Khomeini St, Hasan Abad Sq
City
Tehran
Province
Tehran
Postal code
1136746911
Phone
+98 21 0216 3120
Fax
+98 21 6634 8587
Email
hosp_sina@sina.tums.ac.ir
Web page address
http://sinahospital.tums.ac.ir/

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Hooshyar Honarmand
Street address
Valiasr Square, Keshavarz Boulevard, 16 Azar St., Poursina St.
City
Tehran
Province
Tehran
Postal code
1417653911
Phone
+98 21 81631
Email
tumspr@tums.ac.ir
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
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Hooshyar Honarmand
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Medical Pharmacy
Street address
Sina Hospital, Imam Khomeini St, Hasan Abad Sq
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Person responsible for scientific inquiries

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Hooshyar Honarmand

Position
Assistant Professor

Latest degree
Specialist

Other areas of specialty/work
Medical Pharmacy

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Person responsible for updating data

Contact

Name of organization / entity
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Position
Assistant Professor

Latest degree
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
According to the items mentioned in the informed consent, patients' information will not be disseminated.

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document
Patient demographic data as well as variable outcome data will be shared after patients are unidentifiable.

When the data will become available and for how long
The data will be available after the study and is expected to be available on the Internet from March 2014.

To whom data/document is available
Medical activists

Under which criteria data/document could be used
The data will be available after obtaining the necessary permits from researchers.

From where data/document is obtainable
Tehran university of medical science

What processes are involved for a request to access data/document
A written request for data must be submitted by the individual.

Comments