Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of the effects of omeprazole and placebo in the prevention of acute gastrointestinal events in hospitalized patients with multiple sclerosis receiving corticosteroid pulse: A Prospective randomized double-blind placebo control clinical trial

Protocol summary

Study aim
Comparison of the effects of omeprazole and placebo in patients with MS receiving corticosteroids pulse in the prevention of acute gastrointestinal complications

Design
A Prospective randomized double-blind placebo control clinical trial

Settings and conduct
In this prospective clinical trial, patients with MS admitted to Sina Hospital who are candidates for corticosteroid pulse are randomly assigned to one of two groups of omeprazole 20 mg daily fasting capsules or placebo after obtaining informed consent. During this study, in case of any of the patients with any dyspepsia, famotidine tablets will be used as PRN with a maximum dose of 40 mg per day. The amount and frequency of famotidine use in both groups will be recorded. And is compared. For all patients, demographic information and underlying diseases and medications are recorded.

Participants/Inclusion and exclusion criteria
Inclusion criteria: 1- Patients with recurrent types of MS between 18 and 65 years and hospitalized 2- Receiving 1 gram of corticosteroid pulse daily for at least 3 days 3- Patient consent to participate in the study Exclusion criteria: 1- Presence or history of peptic ulcer disease or gastroesophageal reflux disease or inflammatory bowel diseases 2- Simultaneous administration of other drugs that cause damage to the gastrointestinal mucosa and increase the risk of ulcers 3-Receiving acid-suppressing drugs such as PPIs and H2R antagonists in a recent week 4- Acute or chronic renal and hepatic failure clcr<30 , child-pughscore<2 5- Pregnancy and lactation 6-Patients who are receiving IVIG or plasma exchange at the same time, except for the corticosteroid pulse.

Intervention groups
Intervention group: Patients receiving Omeprazole 20 mg daily Control group: Patients receiving placebo daily

Main outcome variables
The occurrence of dyspepsia symptoms, The need for using Famotidine, The duration of corticosteroid pulse

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20201210049674N1**
Registration date: **2020-12-29, 1399/10/09**
Registration timing: **registered_while_recruiting**

Last update: **2020-12-29, 1399/10/09**
Update count: **0**

Registration date
2020-12-29, 1399/10/09

Registrant information

Name
Mina Hejazi

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-08-22, 1399/06/01

Expected recruitment end date

2021-03-18, 1399/12/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effects of omeprazole and placebo in the prevention of acute gastrointestinal events in hospitalized patients with multiple sclerosis receiving corticosteroid pulse: A Prospective randomized double-blind placebo control clinical trial

Public title

Comparison of the effects of omeprazole in prevention of gastrointestinal events in patients with multiple sclerosis receiving corticosteroid pulse therapy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with recurrent types of MS between 18 and 65 years and hospitalized Receive 1 gram of corticosteroid pulse daily for at least 3 days Patient consent to participate in the study

Exclusion criteria:

Presence or history of peptic ulcer disease or gastroesophageal reflux disease or inflammatory bowel disease such as colitis and Crohn's disease Simultaneous administration of other drugs that cause damage to the gastrointestinal mucosa and increase the risk of ulcers and bleeding, such as oral corticosteroids, NSAIDs, anticoagulants, antiplatelets, etc Receive acid-suppressing drugs such as PPIs and H2R antagonists in the last week Acute or chronic renal and hepatic failure clcr<30 , child-pughscore<2 Pregnancy and lactation Patients receiving IVIG or plasma exchange at the same time, other than a corticosteroid pulse.

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Data analyser

Sample size

Target sample size: **102**

Randomization (investigator's opinion)

Randomized

Randomization description

Block Randomization with size of 4 based on a table of random numbers

Blinding (investigator's opinion)

Double blinded

Blinding description

The patient, the physician, and the person monitoring the patient are blind to the intervention. This study is a double blinded study The main researcher studies the coding of drugs in groups a and b and is aware of the drug and the placebo of the cans, but remains blind as to which patient receives which drug package code. Researchers who accept patients and give them medication and perform evaluation tests, the data analyzer and patients, are blind to the study groups. It should be noted that the drug and placebo are exactly the same in appearance.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

The Institute of Pharmaceutical Sciences- Tehran University of Medical Sciences

Street address

16 Azar Avenue, Tehran University of Medical Sciences, Faculty of Pharmacy, The Institute of Pharmaceutical Sciences, 2nd floor, Unit 1-219

City

Tehran

Province

Tehran

Postal code

1417613151

Approval date

2020-03-15, 1398/12/25

Ethics committee reference number

IR.TUMS.TIPS.REC.1398.215

Health conditions studied

1

Description of health condition studied

Multiple Sclerosis

ICD-10 code

G35

ICD-10 code description

Multiple sclerosis

2

Description of health condition studied

Gastrointestinal problems

ICD-10 code

K92.9

ICD-10 code description

Disease of digestive system, unspecified

Primary outcomes

1

Description
Dyspepsia symptoms (including abdominal pain, nausea, heartburn, vomiting)
Timepoint
Baseline, at the time of discharge from the hospital, 2 weeks after the discharge
Method of measurement
Direct questioning of the patient and, if necessary, clinical examination

2

Description
The dose of Famotidine as PRN for dyspepsia management
Timepoint
At the time of discharge from the hospital, 2 weeks after the discharge
Method of measurement
Direct observing the patient medical report regarding the dose of drug receiving

3

Description
Defecation changes
Timepoint
Baseline, at the time of discharge from the hospital, 2 weeks after the discharge
Method of measurement
Direct questioning of the patient and, if necessary, clinical examination

Secondary outcomes

1

Description
Duration of receiving corticosteroid pulse
Timepoint
At the time of discharge from the hospital
Method of measurement
Patient medical report

Intervention groups

1

Description
Intervention group: Capsule Omeprazole 20 mg (Sobhan company) once daily
Category
Treatment - Drugs

2

Description
Control group: Capsule placebo once daily
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Sina hospital
Full name of responsible person
Hooshyar Honarmand
Street address
Department of Clinical Pharmacy, Tehran University of Medical Sciences, 16-Azar St., Enghelab Ave.,
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Sponsors / Funding sources

1

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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
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

Mina Hejazi

Position

Pharmacy student

Latest degree

Medical doctor

Other areas of specialty/work

Medical Pharmacy

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

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

Study Protocol

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

Statistical Analysis Plan

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

Informed Consent Form

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

Clinical Study Report

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

Analytic Code

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

Data Dictionary

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