

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jun 2026

Evaluation and comparison of the effect of premedication (Methylprednisolone and Naproxen) with placebo in controlling acute complications of IVIG injection in patients with a diagnosis of neurological disease

Protocol summary

Study aim

Determining the effect of premedication in controlling acute complications of IVIG injection

Design

The clinical trial has three groups (Naproxen and Methylprednisolone and control (placebo)), with parallel groups, one-way blind, randomized, phase 3 on 90 patients using random allocation method for randomization.

Settings and conduct

The study was performed in Al-Zahra and Kashani medical centers in Isfahan. In the three study groups, one hour and six hours after the patient about side effects are asked based on a checklist, which is also evaluated if symptoms are severe. The severity of complications is determined based on clinical evidence, the need for local or immediate intervention, interference with daily activities, or life-threatening criteria based on common terminology criteria for side effects. Vital signs are assessed one hour and six hours later by a nurse to check for hypotension and sinus tachycardia. Due to the fact that the questionnaire is self-assessed and the patient does not know about the received premedication due to the similarity of the drug form, blinding is performed.

Participants/Inclusion and exclusion criteria

All patients with a diagnosis of neurological disease, including myasthenia gravis, Guillain-Barré syndrome, chronic inflammatory demyelinating polyneuropathy (CIDP), etc., who are candidates for IVIG and come to medical centers will be included in the study. There is no age limit and the patient will be excluded from the study if he / she does not want to.

Intervention groups

The first group receives 1 mg / kg methylprednisolone injection before receiving the drug, the second group

receives oral naproxen 500 mg and the third group received placebo.

Main outcome variables

Side effects include sinus tachycardia fever blood pressure abdominal pain back pain nausea vomiting chills flushing and etc

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210206050268N1**

Registration date: **2022-02-05, 1400/11/16**

Registration timing: **registered_while_recruiting**

Last update: **2022-02-05, 1400/11/16**

Update count: **0**

Registration date

2022-02-05, 1400/11/16

Registrant information

Name

Nafiseh sadat Mansouri tehrani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3233 0676

Email address

nm.9311@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-01-05, 1400/10/15
Expected recruitment end date
2022-03-21, 1401/01/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation and comparison of the effect of premedication (Methylprednisolone and Naproxen) with placebo in controlling acute complications of IVIG injection in patients with a diagnosis of neurological disease

Public title
Evaluation of the effect of premedication in controlling acute complications of intravenous immunoglobulin injection

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
All patients with a diagnosis of neurological disease, including myasthenia gravis, Guillain-Barré syndrome, chronic inflammatory demyelinating polyneuropathy (CIDP), etc., who are candidates for IVIG will be included in the study.
Exclusion criteria:
The patient's unwillingness to participate in the study

Age
No age limit

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **90**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients are selected by available sampling from among those referred to medical centers. Each patient is assigned a number based on the time of arrival at the center, which is based on a pre-determined list in the control group or receiving Methylprednisolone or Naproxen. The list of 90 is randomly divided between the three study groups using randomization software and each number in the list belongs to one of the three study groups (receiving Naproxen, receiving Methylprednisolone and control).

Blinding (investigator's opinion)
Single blinded

Blinding description
In this study, participants are explained before obtaining consent and none of them have any information about which group they are in. Since all participants are given

placebo or naproxen and all receive serum to receive the drug (which may or may not contain methylprednisolone), they are not aware of which group they belong to. The data analyzer also analyzes the data without knowing the target group (intervention or control).

Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University of Medical

Street address

No. 3, Ostad Taj Alley, Azar street

City

Isfahan

Province

Isfahan

Postal code

8133845735

Approval date

2021-09-14, 1400/06/23

Ethics committee reference number

IR.MUI.MED.REC.1400.480

Health conditions studied

1

Description of health condition studied

premedication use for intravenous immunoglobulin administration

ICD-10 code

T50.Z15

ICD-10 code description

Adverse effect of immunoglobulin

Primary outcomes

1

Description

Complications of intravenous immunoglobulin injection based on checklist

Timepoint

Evaluation of complications one and six hours after injection

Method of measurement

checklist

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: tablet Naproxen 500 mg 30 minutes before intravenous immunoglobulin injection

Category

Prevention

2

Description

Intervention group: 1 mg/kg Methylprednisolone intravenous 30 minutes before intravenous immunoglobulin injection.

Category

Prevention

3

Description

Control group: Placebo tablets are similar in shape and color to naproxen tablets, which are given half an hour before receiving the drug. Also, all patients receive serum before receiving IVIG.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Kashani hospital

Full name of responsible person

Nafiseh sadat Mansouri tehrani

Street address

Ayatollah Kashani street

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Province

Isfahan

Postal code

8183983434

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Email

kashanihospitallibrary@gmail.com

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shaghayegh Haghjoo Javanmard

Street address

Hezar Jerib St., Isfahan University of Medical Sciences, Building No. 4, Vice Chancellor for Research and Technology

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8174673461

Phone

+98 31 3668 8138

Email

research@mui.ac.ir

Web page address

https://research.mui.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Nafiseh sadat Mansouri tehrani

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Neurology

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Adverse reactions data can be generally shared in each of the three study groups

When the data will become available and for how long

Access period starts 6 months after the results are published

To whom data/document is available

Every one has access.

Under which criteria data/document could be used

Available for meta-analysis.

From where data/document is obtainable

the project via email

What processes are involved for a request to access data/document

By email within a week

Comments