# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

17 Sep 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**

Isfehan

**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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8183983434
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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
**City**
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**Province**
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**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 scientific inquiries

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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**