

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Comparison of the effect and Complications of Failure to do Plasmapheresis Versus Routine Plasmapheresis in Patients with Myasthenia Gravis Candidate for Thymectomy

Protocol summary

Study aim

Comparison of the Effect of Complications of Failure to do Plasmapheresis Versus Routine Plasmapheresis in Patients with Myasthenia Gravis Candidate for Thymectomy

Design

randomization is not done. this study is single blinded with historical controls that analyzer is blinded and conducted in 80 participants and including two groups of intervention (not perform Plasmapheresis group) and control (Plasmapheresis group) groups

Settings and conduct

In this study myasthenia gravis patients which have inclusion criteria are enrolled to the study and they are undergoing thymectomy with the open method or thoracoscopic and the results is compared to control group that went under Plasmapheresis before surgery.

Participants/Inclusion and exclusion criteria

Inclusion criteria: All members of the ossermanI, IIA and IIB groups who are candidate for thymectomy Exclusion criteria: Need to plasmapheresis before the surgery Patient dissatisfaction to entering the study

Intervention groups

Intervention group is the Patients with Myasthenia Gravis Candidate for Thymectomy that receive Failure to do Plasmapheresis intervention control group is the Patients with Myasthenia Gravis Candidate for Thymectomy that receive Plasmapheresis intervention

Main outcome variables

Blood volume, Duration of admission in ICU, Duration of admission in the ward

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190205042629N1**

Registration date: **2019-05-25, 1398/03/04**

Registration timing: **registered_while_recruiting**

Last update: **2019-05-25, 1398/03/04**

Update count: **0**

Registration date

2019-05-25, 1398/03/04

Registrant information

Name

Yousef Yousefi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3801 2753

Email address

yousefiy961@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-04-21, 1398/02/01

Expected recruitment end date

2020-04-20, 1399/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect and Complications of Failure to do Plasmapheresis Versus Routine Plasmapheresis in Patients with Myasthenia Gravis Candidate for

Thymectomy

Public title

Comparison of the effect and Complications of Failure to do Plasmapheresis in Patients with Myasthenia Gravis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

All members of the ossermanI, IIA and IIB groups who are candidate for thymectomy

Exclusion criteria:

Need to plasmapheresis before the surgery Patient dissatisfaction to entering the study

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Data analyser

Sample size

Target sample size: 80

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study only the analyzer is blinded to the study. The analyzer is not knowing which the case and control group is.

Placebo

Used

Assignment

Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Mashhad University of Medical Sciences

Street address

Central Building of Mashhad University of Medical Sciences (Ghorshi), Daneshgah 16, Daneshgah Street

City

Mashhad

Province

Razavi Khorasan

Postal code

9138813944

Approval date

2019-01-27, 1397/11/07

Ethics committee reference number

IR.Mums.medical.rec.1397.516

Health conditions studied

1

Description of health condition studied

Myasthenia Gravis

ICD-10 code

G70.0

ICD-10 code description

Myasthenia gravis

Primary outcomes

1

Description

Blood volume

Timepoint

after surgery

Method of measurement

Collecting the amount of blood in the surgery

2

Description

Duration of admission in ICU

Timepoint

after surgery

Method of measurement

Total number of days hospitalized

3

Description

Duration of admission in the bard

Timepoint

after surgery

Method of measurement

Total number of days hospitalized

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Failure to perform plasmapheresis which is a plasma extraction technique that allows for the removal of immunoglobulins and pro-inflammatory factors, such as cryoglobulins and lipoproteins, which are the cause of many diseases. The amount and frequency of plasma required in this situation are partly optional. extracted plasma is replaced with albumin and saline and It is estimated that 2 liters of plasma replacement will remove 80% of circulating antibodies, which will

reduce acetylcholine antibody levels within 3-5 days.

Category

Treatment - Other

2

Description

Control group: plasmapheresis before the surgery which is a plasma extraction technique that allows for the removal of immunoglobulins and pro-inflammatory factors, such as cryoglobulins and lipoproteins, which are the cause of many diseases. The amount and frequency of plasma required in this situation are partly optional. extracted plasma is replaced with albumin and saline and It is estimated that 2 liters of plasma replacement will remove 80% of circulating antibodies, which will reduce acetylcholine antibody levels within 3-5 days.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Ghaem Hospital

Full name of responsible person

Yousef Yousefi

Street address

Ahmad Abad ave.

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0098

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Email

yousefiy961@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaghodi

Street address

Central Building of Mashhad University of Medical Sciences (Ghorshi), Daneshgah 16, Daneshgah street

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ramresearch@mums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Reza Bagheri

Position

associate professor

Latest degree

Specialist

Other areas of specialty/work

General Surgery

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Email

yousefiy961@mums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Reza

Position

associated professor

Latest degree

Specialist

Other areas of specialty/work

Internal Medicine

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Person responsible for updating data

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Yousef

Position

student

Latest degree

Medical doctor

Other areas of specialty/work

Internal Medicine

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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

Not applicable

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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

All data can be shared after patients are made unidentifiable.

When the data will become available and for how long

Data can be accessible 6 months after results are published

To whom data/document is available

Data will be available for researchers in universities and other scientific institutes

Under which criteria data/document could be used

Carrying out analysis on data is permitted.

From where data/document is obtainable

Data can be accessible through sending an email to the corresponding author

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

After sending a request email to the corresponding author, data will be sent in 1 month

Comments