Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 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 befor 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)

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+98 51 3801 2753

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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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
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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
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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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

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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