Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Treatment effect of Rituximab in myasthenia gravis patients resistant to the standard treatment

Protocol summary

Study aim
In this study, the treatment effect of Rituximab in Iranian myasthenia gravis patients resistant to the standard treatment, will be assessed.

Design
This is a prospective, phase 2 clinical trial without parallel groups.

Settings and conduct
This study will conduct in Alzahra hospital of Esfahan. Doctor will visit the patients at the time of enrollment and 3, 6, 9, and 12 months later.

Participants/Inclusion and exclusion criteria
Inclusion criteria: The patient has myasthenia gravis disease (according to AB test, RNS test, Edrophonium test, and Chest MDCT for thymus evaluation); patient resist to standard treatment for myasthenia gravis (including corticosteroid and azathioprine); The patient doesn't have Eaton Lambert syndrome; The patient doesn't administrate unconventional medications (herbal, acupuncture, etc.); Desire of the patient to participate in this study and Signing Written Informed Consent. Exclusion Criteria: Side effects of the drug occur which necessitate the discontinuation of the drug (The most severe side effects include: lethal injection reactions, hypersensitivity reactions, pancytopenia, infection, and organ dysfunction).

Intervention groups
There will be oneIntervention group in this study. All patients will be treated with rituximab. It will be given as one gram in the first week, one gram in the third week, and then one gram in the sixth month intravenousy (in normal saline solution).

Main outcome variables
Clinical status of the patients; Amount of daily activities in myasthenia gravis patients; Quality of patient's life; Signs and symptoms of myasthenia gravis; and Post-intervention Status of the patients

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190324043105N2**
Registration date: **2020-06-23, 1399/04/03**
Registration timing: **retrospective**

Last update: **2020-06-23, 1399/04/03**
Update count: **0**

Registration date
2020-06-23, 1399/04/03

Registrant information

Name
Alireza Eishi Oskouei

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 31 3668 3554

Email address
alireza.eishi@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-01-01, 1397/10/11

Expected recruitment end date
2020-01-01, 1398/10/11

Actual recruitment start date
2019-06-20, 1398/03/30

Actual recruitment end date
2020-06-01, 1399/03/12

Trial completion date
2020-07-21, 1399/04/31

Scientific title

Treatment effect of Rituximab in myasthenia gravis patients resistant to the standard treatment

Public title
Effect of Rituximab in treatment of myasthenia gravis
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
The patient has myasthenia gravis disease (positive AB test for AChR and MUSK *, evidence of myasthenia gravis disease in RNS test, positive Edrophonium test in the patient, and Chest MDCT for thymus involvement). * in Double Seronegative patients, both of these antibodies are negative; Therefore, the other 3 criteria used for diagnosis. In the patients positive for Anti AchR or negative for both antibodies, these characteristics must present: resistance to corticosteroid therapy or is contraindication; resistance to azathioprine treatment or its side effects occur which necessitate the discontinuation of the drug. In the patients positive for Anti MUSK, resistance to corticosteroid therapy or is contraindication, must occur. The patient doesn't have Eaton Lambert syndrome. The patient doesn't administrate unconventional medications (herbal, acupuncture, and etc.). Desire of the patient to participate in this study and Signing Written Informed Consent.
Exclusion criteria:
Age
From **18 years** old to **75 years** old
Gender
Both

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **10**
Actual sample size reached: **14**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Other
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethical Committee of Isfahan University of Medical Sciences
Street address
Isfahan University of Medical Sciences, Hezar Jarib Ave., Isfahan, Iran
City
Isfehan
Province
Isfehan
Postal code
81746 73461
Approval date
2019-06-16, 1398/03/26
Ethics committee reference number
IR.MUI.MED.REC.1398.145

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
Clinical status of the patients
Timepoint
At the time of enrolling the patient to study, and then every 3 moths in the following period of 1 year
Method of measurement
MGFA Clinical Classification Scale

2

Description
amount of daily activities in myasthenia gravis patients
Timepoint
At the time of enrolling the patient to study, and then every 3 moths in the following period of 1 year
Method of measurement
MG-ADL scale

3

Description
quality of patient's life
Timepoint
At the time of enrolling the patient to study, and then every 3 moths in the following period of 1 year
Method of measurement
MGQOL15

4

Description

signs and symptoms of myasthenia gravis

Timepoint

At the time of enrolling the patient to study, and then every 3 moths in the following period of 1 year

Method of measurement

MG Composite Scale

5

Description

Post-intervention Status of the patients

Timepoint

after 6 and 12 months after the beginning of study

Method of measurement

MGFA Post-intervention Status

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Rituximab; Patients will be treated with rituximab. It will be given as one gram in the first week, one gram in the third week, and then one gram in the sixth month intravenousy (in normal saline solution).

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Al-Zahra University Hospital

Full name of responsible person

Mahshid Golagha

Street address

EMG Department, Alzahra University Hospital, Soffeh Blvd., Isfehan

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8174675731

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mahshidgolagha32@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Dr Shaghayegh Haghjoo

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Isfahan University of Medical Science, Hezar Jarib Street, Isfehan

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shaghayegh.haghjoo@gmail.com

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

Mahshid Golagha

Position

Medical Intern

Latest degree

Medical doctor

Other areas of specialty/work

Neuroscience

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
Keivan Basiri

Position
Associate professor

Latest degree
Subspecialist

Other areas of specialty/work
Neurology

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Person responsible for updating data

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Alireza Eishi Oskouei

Position
General Practitioner

Latest degree
Medical doctor

Other areas of specialty/work
Neuroscience

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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
after finishing this trial, MGFA Clinical Classification Scale, MG-ADL scale, MG Composite Scale, MGQOL15, and MGFA Post-intervention Status scores of all patients will be shared with all researchers.

When the data will become available and for how long
starting 6 months after publication

To whom data/document is available
The data will be availabe only to people working in academic institutions.

Under which criteria data/document could be used
the deidentified individual participant data will be available only for research purposes.

From where data/document is obtainable
alireza.eishi@yahoo.com

What processes are involved for a request to access data/document
by sending his/her request to mentioned Email, within less than a month: alireza.eishi@yahoo.com

Comments