

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Oct 2026

Evaluation of efficacy and safety of Zytux™ (Rituximab) in refractory myasthenia gravis patients

Protocol summary

Study aim

Evaluation of efficacy and safety of Zytux™ (Rituximab) in refractory myasthenia gravis patients

Design

This phase 4 prospective, single-arm, open-label, pre-post clinical trial study will be conducted in 30 patients with refractory myasthenia gravis.

Settings and conduct

This multi-center study will be conducted in patients with refractory myasthenia gravis in six different cities of Iran with a follow-up duration of 48 weeks. Zytux™ (Rituximab) will be administered to the eligible patients 2 times at day 0 and 15, followed by one single injection 6 months later. The outcomes will be assessed and recorded by a physician through 48 weeks of monitoring of the patients.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Generalized Non-Thymomatous myasthenia gravis patients, Not having previous treatment with rituximab, Refractory to standard treatment or contraindicated including corticosteroid or Azathioprine, Age between 18 and 80 years Exclusion criteria: Pregnancy, Planning for pregnancy in the following year, Lactation, Active infection, HBsAg+ OR HBV DNA Positive, Prior malignancy, Hypersensitivity reactions or anaphylactic shock to rituximab, Major renal disease, Major Hepatic disease, Cardiac Arrhythmia history, Occular myasthenia gravis, Thymomatous myasthenia gravis, Major Psychiatric disease, Doing Thymectomy

Intervention groups

The therapeutic schema is rituximab 1000 mg, 2 times at day 0 and 15, followed by one single injection (1000 mg) 6 months later. However, rituximab infusion will be administered sooner if myasthenic symptoms reappear and interfere with daily life activities of patient (the interval between Rituximab infusions should be at least three months).

Main outcome variables

Changes in the mean dose of corticosteroid used by patients

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150303021315N18**

Registration date: **2020-05-23, 1399/03/03**

Registration timing: **registered_while_recruiting**

Last update: **2020-05-23, 1399/03/03**

Update count: **0**

Registration date

2020-05-23, 1399/03/03

Registrant information

Name

Nassim Anjidan

Name of organization / entity

Orchid Pharmed

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-02-11, 1398/11/22

Expected recruitment end date

2021-02-10, 1399/11/22

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Evaluation of efficacy and safety of Zytux™ (Rituximab) in refractory myasthenia gravis patients

Public title
Evaluation of efficacy and safety of Zytux™ (Rituximab) in refractory myasthenia gravis patients

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Generalized Non-Thymothamous patients with myasthenia gravis patients including MuSK Antibody positive, AChR Antibody positive, and Seronegative myasthenia gravis patients. Not having previous treatment with rituximab. Refractory to standard treatment or contraindicated including Corticosteroid dependency (taking at least 2 months of 1mg/kg corticosteroid medications and has not responded properly, or being stable with steroid therapy, but during tapering down the medication up to 30 mg alternative or 15 mg daily, has experienced a relapse of the disease); Having contraindication of corticosteroid therapy; Not responder to Azathioprine (2-3 mg/kg) therapy for at least 9 months of taking the medication or because of occurrence of adverse effects of Azathioprine the medication has been stopped. Aged greater or equal to 18, and lesser or equal to 80.
Exclusion criteria:
 Pregnancy Planning for pregnancy in the following year
 Lactation Active infection HBsAg+ OR HBV DNA Positive
 Prior malignancy Hypersensitivity reactions or anaphylactic shock to rituximab Major renal disease Major Hepatic disease Cardiac Arrhythmia history Occular myasthenia gravis Thymomathous myasthenia gravis Major Psychiatric disease Doing Thymectomy

Age
From **18 years** old to **80 years** old

Gender
Both

Phase
4

Groups that have been masked
No information

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Tehran University of Medical Sciences

Street address

No. 23, 16th Azar Ave., Keshavarz Blvd.

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1417863181

Approval date

2020-02-11, 1398/11/22

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1398.879

Health conditions studied

1

Description of health condition studied

Myasthenia gravis

ICD-10 code

G70

ICD-10 code description

Myasthenia gravis and other myoneural disorders

Primary outcomes

1

Description

Changes in the mean dose of corticosteroid used by patients

Timepoint

day 0, day 15, week 12, week 24, week 36, week 48

Method of measurement

Patient's concomitant medication

Secondary outcomes

1

Description

Safety of Zytux™ (Rituximab) in refractory myasthenia gravis patients

Timepoint

day 0, day 15, week 12, week 24, week 36, week 48

Method of measurement

Physical Examination

2

Description

Time to relapse from the onset of treatment

Timepoint

day 0, day 15, week 12, week 24, week 36, week 48

Method of measurement

Physical Examination

3

Description

Changes in AChR and MuSK antibody levels

Timepoint

day 0 and week 48

Method of measurement

The Serum titer of AChR and MuSK antibodies

4

Description

Changes in the mean dose of pyridostigmine used by patients

Timepoint

day 0, day 15, week 12, week 24, week 36, week 48

Method of measurement

Patient's concomitant drugs during treatment

5

Description

Changes in CD19 and CD20 levels

Timepoint

week 7, week 24

Method of measurement

Flow Cytometry

Intervention groups

1

Description

The therapeutic process consists of two cycles. In cycle 1, Zytux™ 1000 mg (Aryogen-Pharmed Rituximab concentrated solution of 10mg/ml made for infusion) will be administered 2 times at day 0 and 15 and one single infusion (1000 mg) 6 months later in cycle 2. However, Zytux™ will be administered sooner if myasthenic symptoms reappear and interfere with the daily life activities of the patient (the interval between Zytux™ infusions should be at least three months).

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shariati hospital

Full name of responsible person

Dr Farzad Fatehi

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Recruitment center

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Recruitment center

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Sina hospital

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Name of recruitment center
Emam Reza hospital
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
AryoGen Pharmed Co.
Full name of responsible person
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Email
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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

AryoGen Pharmed Co.

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Industry

Person responsible for general inquiries

Contact

Name of organization / entity
Orchid Pharmed Co.
Full name of responsible person
Nassim Anjidani
Position
Medical Department Manager
Latest degree
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Person responsible for scientific inquiries

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Person responsible for updating data**Contact****Name of organization / entity**

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available