

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 2026

efficacy of rituximab in treatment of plasma exchange refractory TTP

Protocol summary

Summary

this clinical trial study was non randomize, single blind study without placebo in ten refractory TTP patients to plasma exchange at least seven days have been treated with plasma exchange and with a series of laboratory tests rule out secondary causes of ttp. informed written consents were obtained then Patients treated with rituximab weekly for 4 weeks finally response rate (RR), Disease free survival (DFS) and overall survival (OS) was evaluated.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017012232125N1**

Registration date: **2017-07-25, 1396/05/03**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-07-25, 1396/05/03

Registrant information

Name

ali reza sadeghi

Name of organization / entity

esfahan university

Country

Iran (Islamic Republic of)

Phone

+98 31 3673 3910

Email address

a.sadeghi@med.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

investigator

Expected recruitment start date

2010-03-21, 1389/01/01

Expected recruitment end date

2016-03-20, 1395/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

efficacy of rituximab in treatment of plasma exchange refractory TTP

Public title

the effect of rituximab in ttp patient refractory to plasmexchange

Purpose

Treatment

Inclusion/Exclusion criteria

exclusion: viral infection, malignancy, autoimmune disease, drug (cyclosporine, ticlopidine, ...) inclusion: criteria for ttp diagnosis

Age

No age limit

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **10**

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 committees1**Ethics committee****Name of ethics committee**

medical university of esfahan

Street address

medicah school hezar jarib avenue esfahan

City

esfahan

Postal code**Approval date**

2012-11-21, 1391/09/01

Ethics committee reference number

391368

Health conditions studied1**Description of health condition studied**

TTP

ICD-10 code

D69

ICD-10 code description

.thrombotic thrombocytopenic purpura

Primary outcomes1**Description**

PLT-LDH

Timepoint

daily check to recieve to goal of treatmeant

Method of measurement

laboratory

Secondary outcomes1**Description**

BUN CR

Timepoint

at first daily check then weekly and monthly

Method of measurement

laboratory

2**Description**

level of consciousness

Timepoint

at first daily check then weekly and monthly

Method of measurement

clinical examination

3**Description**

drug complication

Timepoint

at first daily check then weekly and monthly

Method of measurement

clinical examination- laboratory

Intervention groups1**Description**

TTP patients that rule out secondary cause undergo treatment with monoclonal anti body (Rituximab) . this drug is anti CD20 ,marcker on the B Lymphocyte . Rituximab dose was 375 mg/m2 weekly for 4 weeks. Rituximab manufacture ROCH COMPANY

Category

Treatment - Drugs

Recruitment centers1**Recruitment center****Name of recruitment center**

azahra hospital

Full name of responsible person

ali reza sadeghi

Street address

esfahan- sofe aven

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Sponsors / Funding sources1**Sponsor****Name of organization / entity**

vice chancellor for research of esfahan university of medical sciences

Full name of responsible person

ali reza sadeghi

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hezarjerib avenue esfahan iran

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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

vice chancellor for research of esfahan university of

medical sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

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Person responsible for general inquiries

Contact

Name of organization / entity
ESFAHAN UNIVERSITY OF MEDICINE
Full name of responsible person
ali reza sadeghi MD
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty