

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jul 2026

The efficacy of rituximab for recalcitrant Pemphigus Vulgaris in the reduction of prednisolone dose

Protocol summary

Summary

Background: Pemphigus vulgaris is an autoimmune blistering disease in which pathogenic autoantibodies are responsible. The immunosuppressive agents which target autoantibodies production could suppress disease activity. Although corticosteroid is the choice of therapy, the efficacy and safety of other immunosuppressive agents such as rituximab which selectively target CD20 B cells, are under investigation. Objective and main outcome: To determine the efficacy of rituximab in the reduction of prednisolone dose. Exclusion and inclusion criteria: the patients with refractory and recurrent Pemphigus vulgaris that are candidates for rituximab will be enrolled. Exclusion criterion are pregnancy and breast feeding, history of sensitization to murine protein, hepatitis B carriers, cardiac arrhythmias & angina pectoris, high tumor burden, active infections. Design, setting and conduct: The enrolled patients will be taken rituximab 500 mg intravenously weekly for 4 weeks in each cycle. In the regular examinations (weekly for 1 month and then monthly after injecting rituximab), the therapeutic effects will be estimated by clinical remission including, new blisters per day, Nikolsky's sign and epithelialization over the denuded surfaces, plus side effects and relapse. The dose of oral prednisolone prior to treatment, 3 months, 6 months and the final in the last visit for each patient will be written. Finally the results will be analyzed to determine the efficacy and safety of rituximab in the treatment of pemphigus vulgaris.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201111022704N2**

Registration date: **2011-12-03, 1390/09/12**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2011-12-03, 1390/09/12

Registrant information

Name

Somayeh Khezri

Name of organization / entity

Razi hospital

Country

Iran (Islamic Republic of)

Phone

00982155609951-00982155609951

Email address

khezri@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice-chancellor for Research of Tehran University of Medical Sciences

Expected recruitment start date

2007-03-21, 1386/01/01

Expected recruitment end date

2011-09-21, 1390/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The efficacy of rituximab for recalcitrant Pemphigus Vulgaris in the reduction of prednisolone dose

Public title

The efficacy of rituximab for recalcitrant Pemphigus Vulgaris in the patients of Razi hospital from 2007 to 2011

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients with Pemphigus Vulgaris who are candidates for rituximab (failure to respond or frequent recurrences under long-term (months to years) oral corticosteroids more than 10 mg daily with or without additional immunosuppressive therapy; or oral corticosteroids intolerance with or without short and long-term oral corticosteroids side effects) Exclusion criterion were: pregnancy and breast feeding; history of sensitization to murine protein; hepatitis B carriers; cardiac arrhythmias & angina pectoris; high tumor burden; active infections

Age

No age limit

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: 40

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 with supervision of Vice-chancellor for Research of Tehran University of Medical Sc

Street address

Vice-chancellor for Research of Tehran University of Medical Sciences, 205th room, 1st floor, Education Bldg, Poursina st.

City

Tehran

Postal code

1417613151

Approval date

2011-10-07, 1390/07/15

Ethics committee reference number

21166

Health conditions studied

1

Description of health condition studied

Pemphigus vulgaris

ICD-10 code

L10.0

ICD-10 code description

Pemphigus vulgaris

Primary outcomes

1

Description

therapeutic effect (new blisters per day, Nikolsky's sign and epithelialization over the denuded surfaces)

Timepoint

weekly for 1 month and then monthly after injecting rituximab

Method of measurement

clinical examination

2

Description

The dose of oral prednisolone

Timepoint

prior to treatment, next 3 months, next 6 months and the final in the last visit

Method of measurement

mg per day

Secondary outcomes

1

Description

side effects

Timepoint

weekly for 1 month and then monthly after injecting rituximab

Method of measurement

clinical examination

Intervention groups

1

Description

rituximab 500 mg intravenously weekly for 4 weeks in each cycle

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Razi Hospital
Full name of responsible person
Kamran Balighi
Street address
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Person responsible for scientific inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice-chancellor for Research of Tehran University of Medical Sciences
Full name of responsible person
Dr.Shahin Akhound Zadeh
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Research department of medical school of Tehran University of Medical Sciences,205th room,1st floor,Education Bldg.,Poursina st.
City
Tehran

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 Tehran 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

Person responsible for general inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences
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Somayeh Khezri
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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