# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

19 Sep 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 cariers,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 coricosteroids side effects) Exclusion criterion were: pregnancy and breast feeding؛history of sensitization to murine protein؛hepatitis B cariers؛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**
Razi Hospital,Vahdat_e_eslami st.
**City**
Tehran

## 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
**Street address**
Research department of medical school of Tehran University of Medical Sciences,205th room,1st floor,Education Bldg.,Poursina st.
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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
**Full name of responsible person**
Somayeh Khezri
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resident of dermatology
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## Person responsible for scientific inquiries

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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*