

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

07 Jun 2026

### Evaluation of therapeutic effect of prednisolone + dapson with prednisolone+imurane in pemphigus vulgaris treatment

#### Protocol summary

##### Summary

The aim of this study is: Evaluation of therapeutic effect of prednisolone + dapson with prednisolone+imurane in pemphigus vulgaris treatment. This study is a randomized clinical trial. Population of patients with pemphigus vulgaris visit in, a dermatology clinic of Sina hospital or Sheikh Alrayys clinic, Tabriz, Iran. Inclusion criterion: patients with pemphigus vulgaris, that their disease was detected by the clinical or pathological evidence of initial tests with pemphigus vulgaris. Exclusion criterion: patients who were G6PDD. Thirty patients were selected and randomly divided into two groups; First group treatment with prednisolone + imurane and the second group treatment with prednisolone + dapson. The study has begun from 2011/12/22. The patients for eleven months and at weeks zero, one, two, three, and four, two months later, three months later, five months later, seven months later, nine months later and eleven months later of treatment, are evaluated for recovery and complications the patient has been taking a careful history and physical examination as well as the series of experiments, two groups were compared.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201307133566N2**  
Registration date: **2013-08-03, 1392/05/12**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2013-08-03, 1392/05/12

##### Registrant information

##### Name

Hamide Azimi

##### Name of organization / entity

Tabriz University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 1540 6612

##### Email address

azimih@tbzmed.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Tabriz university of medical sciences

##### Expected recruitment start date

2012-09-19, 1391/06/29

##### Expected recruitment end date

2013-08-20, 1392/05/29

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluation of therapeutic effect of prednisolone + dapson with prednisolone+imurane in pemphigus vulgaris treatment

##### Public title

Effect of dapson in treatment of pemphigus vulgaris

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criterion: patients with pemphigus vulgaris, that their disease was detected by the clinical or pathological evidence of initial tests with pemphigus vulgaris.

Exclusion criterion: patients who were G6PDD.

##### Age

No age limit

**Gender**

Both

**Phase**

2-3

**Groups that have been masked**

No information

**Sample size**

Target sample size: 30

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

**Blinding (investigator's opinion)**

Not blinded

**Blinding description**

**Placebo**

Not used

**Assignment**

Parallel

**Other design features**

**Secondary Ids**

empty

**Ethics committees**

1

**Ethics committee**

**Name of ethics committee**

Tabriz university of medical sciences

**Street address**

azady avenue,golgasht avenue

**City**

tabriz

**Postal code**

iran

**Approval date**

2012-09-15, 1391/06/25

**Ethics committee reference number**

9189

**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**

Severity of damage

**Timepoint**

The patients for eleven months and at weeks zero, one, two, three, and four, two months later, three months later, five months later, seven months later, nine months later and eleven months later of treatment follow up

**Method of measurement**

Physical examination

**Secondary outcomes**

1

**Description**

Lipid profile

**Timepoint**

The patients for eleven months and at weeks zero, one, two, three, and four, two months later, three months later, five months later, seven months later, nine months later and eleven months later of treatment follow up

**Method of measurement**

Lab tests

2

**Description**

HTN

**Timepoint**

the patients for eleven months and at weeks zero, one, two, three, and four, two months later, three months later, five months later, seven months later, nine months later and eleven months later of treatment follow up

**Method of measurement**

lab

3

**Description**

Liver function test

**Timepoint**

The patients for eleven months and at weeks zero, one, two, three, and four, two months later, three months later, five months later, seven months later, nine months later and eleven months later of treatment follow up

**Method of measurement**

Lab tests

**Intervention groups**

1

**Description**

control: treatment by prednisolone+imurane  
prednisolone 1-2mg/kg/day imurane:2-3mg/kg/day

**Category**

Treatment - Drugs

2

**Description**

Interventional treatment by prednisolone + dapson  
prednisolone 1-2mg/kg /day dapson 100-200mg/day

### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

**Name of recruitment center**

Dermatology clinic of Sina hospital

**Full name of responsible person**

Dr. Azimi Dermatologist

**Street address**

Sina hospital Azadi Avenue

**City**

Tabriz

### 2

#### Recruitment center

**Name of recruitment center**

Sheikh Alrayys clinic

**Full name of responsible person**

Dr. Azimi dermatologist

**Street address**

Azadi avenue

**City**

Tabriz

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Tabriz university of medical sciences, assistance  
research

**Full name of responsible person**

Dr. Meshkini

**Street address**

Golgasht Avenue, Azadi Avenue Tabriz

**City**

Tabriz

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor  
organization/entity?**

Yes

**Title of funding source**

Tabriz university of medical sciences, assistance  
research

**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**

Tabriz university of medical sciences

**Full name of responsible person**

Dr. Hamide Azimi

**Position**

Dermatologist

**Other areas of specialty/work**

**Street address**

Sina hospital, Azadi Avenue

**City**

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**Postal code**

5163639888

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azimi@tbzmed.ac.ir

**Web page address**

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Tabriz university of medical sciences

**Full name of responsible person**

Dr. Hamide Azimi

**Position**

Dermatologist

**Other areas of specialty/work**

**Street address**

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**Web page address**

## Person responsible for updating data

### Contact

## 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*