

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

06 Jun 2026

### Comparison of therapeutic effect an Iranian traditional medicinal local drug and placebo in the treatment of cutaneous lesions of Pemphigus Vulgaris.

#### Protocol summary

##### Summary

The aim of this study is investigating the effect of a chosen local herbal drug from Persian medicine in the treatment of cutaneous lesions caused by Pemphigus vulgaris. This study will be performed on 20 patients with confirmed diagnosis who are hospitalized in the dermatology department of shahid Faghihi hospital; dependent on shiraz University of Medical Sciences; who had signed informed consent. Right- or left-sided lesions will randomized for treatment with Iranian topical medicinal drug or placebo. The treatments are applied locally twice a day and the wounds are evaluated in 0, 15 and 30 days after starting the treatments by examining the wound extent, recovery rate, and Epithelialization. The measurements are performed with ruler and the widest wound diameter is measured. By using the Epithelialization index equation, the improvement of Epithelialization could be quantified. Lastly by using statistical analysis, the effects of medicinal product will be analyzed.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2013120815720N1**

Registration date: **2014-04-06, 1393/01/17**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2014-04-06, 1393/01/17

##### Registrant information

###### Name

fatemeh atarzadeh

##### Name of organization / entity

Tehran univercity of medical sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 5560 1274

##### Email address

f\_atarzadeh@razi.tums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Tehran University of Medical Science

##### Expected recruitment start date

2013-12-10, 1392/09/19

##### Expected recruitment end date

2014-07-10, 1393/04/19

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of therapeutic effect an Iranian traditional medicinal local drug and placebo in the treatment of cutaneous lesions of Pemphigus Vulgaris.

##### Public title

The efficacy of an Iranian traditional medicinal drug in the treatment of cutaneous lesions of Pemphigus Vulgaris.

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: patients who has confirmed Pemphigus vulgaris in clinical manifestation and pathology and direct immunofluorescence; who has been admitted for

the first time or in the relapse of disease; having two symmetrical lesions on the trunk or extremities; signing of informed consent. exclusion criteria: Pregnant or nursing patients; having drug sensitivity; face lesions; infected lesions.

**Age**

No age limit

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

No information

**Sample size**

Target sample size: 20

**Randomization (investigator's opinion)**

Randomized

**Randomization description****Blinding (investigator's opinion)**

Double blinded

**Blinding description****Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Research Institute for Islamic and Complementary  
Medicine (RICM)

**Street address**

Pyrnia Alley, Lalezarno Ave. Jomhoori Eslami St.  
Tehran, IRAN

**City**

Tehran

**Postal code****Approval date**

2013-05-27, 1392/03/06

**Ethics committee reference number**

114/ط م/26پ

**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**

diameter of skin pemphigus lesions

**Timepoint**

0, 15, 30

**Method of measurement**

ruler (mm)

**Secondary outcomes****1****Description**

epithelization index

**Timepoint**

0, 15, 30

**Method of measurement**

Maximum diameter at the baseline - Maximum diameter  
at the end of study)/ Maximum diameter at the baseline  
\* 100

**Intervention groups****1****Description**

applying local traditional medicinal gel drug to the lesion  
in intervention side twice daily in 30 days.

**Category**

Treatment - Drugs

**2****Description**

applying local placebo gel drug to the lesion in control  
side twice daily in 30 days.

**Category**

Placebo

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Shahid Faghihi Hospital Shiraz

**Full name of responsible person**

Ladan Dastgheib

**Street address**

Zand Avenue, Shiraz, Iran

**City**

Shiraz

**Sponsors / Funding sources****1****Sponsor**

**Name of organization / entity**

Tehran University Of Medical Sciences

**Full name of responsible person**

Dariush Mahmoodi

**Street address**

Office of Vice Chancellor to Research, Third floor,  
Faculty of Triditional Medicine, Behesht St., Vahdat  
Eslami st., Tehran

**City**

Tehran

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

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, department-of-traditional-medicine

**Full name of responsible person**

Fatemeh Atarzadeh

**Position**

MD

**Other areas of specialty/work****Street address**

No. 59, Ghasrodasht, Shiraz

**City**

Shiraz

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**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Tehran University of Medical Sciences Faculty of

Pharmacy

**Full name of responsible person**

Gholamreza Amin

**Position**

PHD

**Other areas of specialty/work****Street address**

Enghelab Street, Tehran University of Medical  
Sciences, School of Pharmacy

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amin@tums.ac.ir

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

School of Iranian traditional medicine, Tehran  
University of Medical Sciences

**Full name of responsible person**

fatemeh atarzadeh

**Position**

MD

**Other areas of specialty/work****Street address**

Behesht Clinic, Behesht St., Vahdat-e Eslami st.  
(South Hafiz)

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**Web page address****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*