

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 university of medical sciences

Country

Iran (Islamic Republic of)

Phone

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Email address

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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 Traditional 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**

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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

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

City

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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

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

Behesht Clinic, Behesht St., Vahdat-e Eslami st.
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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