Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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

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Name of organization / entity

Tehran univercity of medical sciences

Country

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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 śkin 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 Tridtional 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
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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