

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 2026

Effectiveness of topical pilocarpine as a cholinomimetic on refractory oral lesions :a single blinded, randomized controlled trial

Protocol summary

Study aim

The aim is to investigate the effect of pilocarpine drop as a cholinomimetic on recalcitrant mouth lesions caused by pemphigus vulgaris and its usage as a future medication.

Design

This is a single-blinded, randomized, controlled trial. this phase 2-3 trial will be parallelly performed on 42 patients.

Settings and conduct

Forty-two patients with recalcitrant mouth lesions referred to the pemphigus clinic at Razi Hospital located in Tehran enter the study. Patients are randomly and equally divided into 2 groups of treatment and placebo and will receive the drug or placebo simultaneously. This study is single-blinded, and none of the patients are informed about the received treatment(pilocarpine or placebo).

Participants/Inclusion and exclusion criteria

The patients diagnosed with pemphigus vulgaris clinically and histo-pathologically are involved with resistant mouth lesions, age 20-70, and involved mouth lesions should not be more than 2-3 in each patient.

Intervention groups

Two groups of intervention and control in this study have been randomly assigned. The intervention group receives drop pilocarpine 4%, and the placebo group receives distilled water as placebo.

Main outcome variables

Evaluating the oral lesions by oral disease severity score (ODSS); assessing the patient satisfaction by visual analogue scale (VAS); evaluating the disease activity by pemphigus area disease activity (PDAI); measuring the size of lesions

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221002056070N1**

Registration date: **2023-11-25, 1402/09/04**

Registration timing: **prospective**

Last update: **2023-11-25, 1402/09/04**

Update count: **0**

Registration date

2023-11-25, 1402/09/04

Registrant information

Name

Nafiseh Esmaili

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 21 5557 5141

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-02-20, 1402/12/01

Expected recruitment end date

2024-08-22, 1403/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness of topical pilocarpine as a cholinomimetic on refractory oral lesions :a single blinded, randomized controlled trial

Public title

The effect of drop pilocarpine on oral lesions in pemphigus vulgaris

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Clinical and histopathological confirmation of pemphigus vulgaris Patients with resistant oral ulcers that have not been treated with systemic drugs or have relapsed after treatment Age between 20-70 Accessible mouth lesions(retromolar trigone)

Exclusion criteria:

oral lesions more than 2-3

Age

From **20 years** old to **70 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant

Sample size

Target sample size: **42**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be assigned into two groups: A(drug) and B(placebo). Block randomization with size of four will be used via random allocation software. To produce a list of random numbers, a number is made by the software. If the number is between 0 and 4, the patients will be allocated to group B. If the number is between 5 and 9 the patient will be placed in group A. The process will be repeated until the eligible patients are included.

Blinding (investigator's opinion)

Single blinded

Blinding description

The drug and placebo (pilocarpine and distilled water) have the same form and are given in the same containers.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

ethics committee of Tehran University of medical science

Street address

Razi Hospital, vahdat eslami square, vahdat eslami avenue, Tehran

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Tehran

Province

Tehran

Postal code

1199663911

Approval date

2022-09-10, 1401/06/19

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1401.446

Health conditions studied**1****Description of health condition studied**

pemphigus vulgaris oral lesions

ICD-10 code

L10.0

ICD-10 code description

Pemphigus vulgaris

Primary outcomes**1****Description**

size of oral lesions

Timepoint

Baseline visit, week 4 and week 8

Method of measurement

Measuring the size of lesions in photos by software, evaluation of patient satisfaction, oral lesion status and disease severity using VAS, ODSS and PDAI questionnaires

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

Pemphigus disease area index (PDAI)

Timepoint

Baseline visit and week 8

Method of measurement

Pemphigus disease area index questionnaire (PDAI)

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

Intervention group: The drug used in this group is drop pilocarpine 4%, which is put in another container to avoid getting identified by the patients. Patients will be using the drug for 8 weeks, twice a day (morning and afternoon). The drug administration will be done via a smeared cotton swab.

Category

2**Description**

Control group: The control group will receive distilled water in the same containers as the intervention group. The process is also done the same as the intervention group (within 8 weeks, twice a day and two drops).

Category

Placebo

Recruitment centers1**Recruitment center****Name of recruitment center**

Razi hospital

Full name of responsible person

Dr. Nafise Esmaeili

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Sponsors / Funding sources1**Sponsor****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

doctor Akbar Fotouhi

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Tehran University of Medical Science, ghods street, keshavarz boulevard

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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

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Academic

Person responsible for general inquiries**Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Dr. Zeinab aryanian

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Dermatology

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

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Position

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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
there is no more information.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available