

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the efficacy and side effects of low dose (≤ 10 mg/day) prednisolone maintenance therapy in pemphigus Vulgaris patients on remission with minimal prednisolone therapy and positive anti-desmoglein 1 and/or 3 antibodies referring to Razi Hospital, Tehran, Iran in 2020.

Protocol summary

Study aim

A comparative study of the efficacy and side effects of low dose (≤ 10 mg/day) prednisolone maintenance therapy in pemphigus vulgaris patients on remission with minimal prednisolone therapy and positive anti-desmoglein 1 and/or 3 antibodies.

Design

Phase 1 clinical trial with a control group, one-way blind (patients), with a sample size of 80 people and with a parallel-group randomized with Block-Randomization system that patients are evaluated for 1 year.

Settings and conduct

A group of 80 pemphigus vulgaris patients will be selected and divided into two groups of 40 based on the severity of primary disease (namely severe and mild). Subsequently, each group will be randomly assigned into two equal subgroups using the Block-Randomization System. The first subgroup in either group will continue to receive low-dose prednisolone ($= < 10$ mg per day) after amelioration of the disease, whereas the second subgroup will discontinue the medication after the disease subsides. Follow-up visits will be scheduled every 3 months at Razi hospital. After 1 year we will evaluate the safety and efficacy of low dose prednisolone. This trial will be single-blinded where only patients are blinded to their treatment allocation.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Pemphigus vulgaris patients in remission phase which is treated with maintenance dose of prednisolone (5-10 mg / day) with positive anti-desmoglein 1 and/or 3 antibodies. Exclusion criteria: Active disease and negative anti desmoglein 1&3 antibodies.

Intervention groups

Intervention group: Prednisolone receiver patients at a dose of 5-10 mg per day in one of the severe or mild subgroups
Control group: Not receiving medication in other subgroups

Main outcome variables

Measuring the recurrence rate and incidence of diabetes, osteoporosis, infection, weight gain, cataracts

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190813044524N1**

Registration date: **2020-04-20, 1399/02/01**

Registration timing: **prospective**

Last update: **2020-04-20, 1399/02/01**

Update count: **0**

Registration date

2020-04-20, 1399/02/01

Registrant information

Name

Matin Sadr

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8878 2293

Email address

m-sadr@student.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-04-27, 1399/02/08

Expected recruitment end date

2020-04-27, 1399/02/08

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the efficacy and side effects of low dose (≤ 10 mg/day) prednisolone maintenance therapy in pemphigus Vulgaris patients on remission with minimal prednisolone therapy and positive anti-desmoglein 1 and/or 3 antibodies referring to Razi Hospital, Tehran, Iran in 2020.

Public title

Prednisolone maintenance therapy in pemphigus vulgaris.

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Pemphigus vulgaris patients on remission phase. Under treatment with low dose prednisolone (5-10 mg/day) maintenance therapy. Positive anti-desmoglein 1 and/or 3.

Exclusion criteria:

Pemphigus vulgaris patients with negative anti-desmoglein. Active phase of the disease

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

- Participant

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization was developed for randomization using the online tool <https://www.sealedenvelope.com/simple-randomiser/v1/list.s>). In this tool, each patient is assigned a number and the patients are randomly divided into two groups. Participant number and group information is only available to the researcher.

Blinding (investigator's opinion)

Single blinded

Blinding description

This study is a single-blind, controlled trial, and the trial is planned in a way that patients do not know belong to which of the two control or experimental groups.

Placebo

Not 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

Central Organization of Tehran University of Medical Sciences, Qods Ave, Keshavarz Blvd., Tehran.

City

Tehran

Province

Tehran

Postal code

1417653761

Approval date

2019-09-02, 1398/06/11

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1398.478

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**

Continuation of the remission phase of the disease.

Timepoint

Before starting the study, Every three months, End of the first year.

Method of measurement

Direct examination by the a dermatologist so that the patient has no skin and/or mucosal manifestations.

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

Diabetes

Timepoint

Before starting the study, Every three months, End of the first year.

Method of measurement

Measurement of blood sugar over the past 3 months (HbA1C) and fasting blood sugar (FBS) and record information in the patient's file by the doctor

2

Description

Osteoporosis

Timepoint

Before starting the study, End of the first year.

Method of measurement

Perform bone mineral densitometry and record information in the patient's file by the physician

3

Description

Increase in infection rate

Timepoint

Before starting the study, Every three months, End of the first year.

Method of measurement

Question about history of the fever, loss of consciousness, headache, shortness of breath, cough, sore throat, abdominal pain, diarrhea and vomiting, dysuria and frequency, abnormal vaginal discharge, redness and warmth of the skin and record information in the patient's file by the physician.

4

Description

Weight gain

Timepoint

Before starting the study, Every three months, End of the first year.

Method of measurement

The patient's weight is measured with the center scale and recorded in the patient's file by the physician.

5

Description

Cataract

Timepoint

Before starting the study, Every three months, End of the first year.

Method of measurement

The question of blurred vision and its severity, if the answer is yes, we will refer her to an ophthalmologist to determine the extent of the conflict (Farabi Hospital). record information in the patient's file based on the sheet provided by the ophthalmologist by the researcher physician

Intervention groups

1

Description

Intervention group: Group 1: Pemphigus Vulgaris patients with mild disease at diagnosis, who are on remission with prednisolone minimal therapy (≤ 10 mg/day which is used as 1 or 2 tablet/s of 5 mg orally every daily/12 hours respectively) and their anti-desmoglein 1 and or 3 antibodies are positive and this drug will continue for 1 year. Prednisolone of Iran Hormone Company is being studied.

Category

Treatment - Drugs

2

Description

Control group: Pemphigus Vulgaris patients with mild disease at diagnosis, who are on remission with prednisolone minimal therapy (≤ 10 mg/day which is used as 1 or 2 tablet/s of 5 mg orally every daily/12 hours respectively) their anti-desmoglein 1,3 antibodies are positive, and taper prednisolone. This drug will be discontinued for 1 year and will not receive any treatment. Prednisolone of Iran Hormone Company is being studied. Prednisolone of Iran Hormone Company is being studied.

Category

Treatment - Other

3

Description

Intervention group 2: Pemphigus Vulgaris patients with moderate-severe disease at diagnosis, who are on remission with prednisolone minimal therapy (≤ 10 mg/day which is used as 1 or 2 tablet/s of 5 mg orally every daily/12 hours respectively) and their anti-desmoglein 1 and or 3 antibodies are positive, and this drug will continue for 1 year. Prednisolone of Iran Hormone Company is being studied. Prednisolone of Iran Hormone Company is being studied.

Category

Treatment - Drugs

4

Description

Control group 2: Pemphigus Vulgaris patients with moderate-severe disease at diagnosis, who are on remission with prednisolone minimal therapy (≤ 10 mg/day which is used as 1 or 2 tablet/s of 5 mg orally every daily/12 hours respectively) their anti-desmoglein 1 and or 3 antibodies are positive and stop prednisolone. This drug will be discontinued for 1 year and will not receive any treatment. Prednisolone of Iran Hormone Company is being studied. Prednisolone of Iran Hormone Company is being studied.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Razi hospital

Full name of responsible person

Hamidreza Mahmoudi

Street address

Razi Hospital, Razi Dead end, Vahdat Eslami Square,
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Email

hr_mahmoody@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Hamidreza Mahmoudi

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Razi hospital, Razi Dead end, Vahdat Eslami Square,
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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

Hamidreza Mahmoudi

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Dermatology

Street address

Razi Hospital, Razi Dead end, Vahdat Eslami Square,
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Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Hamidreza Mahmoudi

Position

Assistant Professor of dermatology

Latest degree

Specialist

Other areas of specialty/work

Dermatology

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Person responsible for updating data

Contact

Name of organization / entity

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Position

Assistant Professor of dermatology

Latest degree

Specialist

Other areas of specialty/work

Dermatology

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All data are shareable, except for patients' pictures, after anonymizing the patients.

When the data will become available and for how long

All data are shareable 6 months after publishing the results.

To whom data/document is available

Researchers working in universities or science institutions or people working in industrial areas can receive the data or other documents on the study.

Under which criteria data/document could be used

The data or the other documents on the research can be used for systematic review or any other purpose provided by having legal permission from the owners of the study.

From where data/document is obtainable

Dr. Hamidreza Mahmoudi E-mail address:
hr_mahmoody@yahoo.com Mobile-phone number:
00989122612946

What processes are involved for a request to access data/document

Using the data or documents is possible after one month, provided having the legal permission of the owners of the study, by one of the authorized people.

Comments