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 wich 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-desmogleion 1 and/or 3.
Exclusion criteria:
Pemphigus vulgaris patients with negative anti-desmogleion. 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 month (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 1or 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 1or 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 1or 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 1or 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, Vahdat Eslami Ave, Tehran, Iran

City
Tehran

Province
Tehran

Postal code
1199663911

Phone
+98 21 5563 0553

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

Street address
Razi hospital, Razi Dead end, Vahdat Eslami Square, Vahdat Eslami Ave, Tehran, Iran

City
Tehran

Province
Tehran

Postal code
1199663911

Phone
+98 21 5563 0553

Email
hr_mahmoody@yahoo.com

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, Vahdat Eslami Ave, Tehran, Iran

City
Tehran

Province
Tehran

Postal code
1199663911

Phone
+98 21 5563 0553

Email
hr_mahmoody@yahoo.com

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

Street address
Razi Hospital, Razi Dead end, Vahdat Eslami Square, Vahdat Eslami Ave, Tehran, Iran

City
Tehran

Province
Tehran

Postal code
1199663911

Phone
+98 21 5563 0553

Email
hr_mahmoody@yahoo.com

Person responsible for updating data

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
Street address
Razi Hospital, Razi Dead end, Vahdat Eslami Square, Vahdat Eslami Ave, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1199663911
Phone
+98 21 5563 0553
Email
hr_mahmoody@yahoo.com

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