

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jul 2026

Pilot Study of the Efficacy of Metformin as an Adjuvant Therapy in Patients with Pemphigus Vulgaris

Protocol summary

Study aim

The evaluation of the metformin efficacy as an adjuvant therapy in the treatment of patients with pemphigus in Mazandaran province.

Design

Clinical trial with community-based and pragmatic control group, with parallel groups, triple blind, randomized

Settings and conduct

Context: Adjuvant treatment of autoimmune diseases (Pemphigus vulgaris) Place and method of study: Mazandaran University of Medical Sciences (skin clinics) Blinded people: patients, researcher, data analyzer

Participants/Inclusion and exclusion criteria

Patients with definite diagnosis of Pemphigus Vulgaris and Foliacea can take part in the study based on their clinical profile, pathologic findings and direct and indirect immunofluorescence, the age of 18 and both sexes (female / male). People under the age of 18 and duration of diagnosis for more than 24 months are excluded from the study.

Intervention groups

control group: Prednisolone plus metformin for placebo Intervention group: Metformin consumer as an adjuvant in the treatment of Pemphigus (plus to the main treatment)

Main outcome variables

IgG1 level; IgG3 Level; serum level of NFkB; serum level of TNFa

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170822035834N2**

Registration date: **2018-03-05, 1396/12/14**

Registration timing: **prospective**

Last update: **2018-03-05, 1396/12/14**

Update count: **0**

Registration date

2018-03-05, 1396/12/14

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 3354 3190

Email address

g.houshmand@mazums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-04-04, 1397/01/15

Expected recruitment end date

2018-07-06, 1397/04/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Pilot Study of the Efficacy of Metformin as an Adjuvant Therapy in Patients with Pemphigus Vulgaris

Public title

Metformin in Pemphigus Vulgaris

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

People diagnosed with their disease, and clinical manifestations and laboratory findings related to

pemphigus (skin manifestations, etc.) have been proven by a dermatologist. And hospitalized in the relevant department. Individual consent to participate in the study age more than 18

Exclusion criteria:

age less than 18 Duration of diagnosis is more than 24 months.

Age

From **18 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients who come to the skin clinic will be randomly assigned to the study using RAS computer software. Therefore, this will be clinically randomized,too.

Blinding (investigator's opinion)

Triple blinded

Blinding description

The drug and placebo were packed in envelopes labeled A and B so that neither the investigator nor the patient knew which one is drug or placebo until the end of the study.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee, Faculty of Medical Sciences, Azad University of Sari

Street address

Khazar Square- Farah Abad Blvd - 18th sea Road - University of the Holy Prophet of Azam- Faculty of Medicine- Department of Physiology and Pharmacology

City

sari

Province

Mazandaran

Postal code

4847191971

Approval date

2018-02-03, 1396/11/14

Ethics committee reference number

IR.IAU.SARI.REC.1396.50

Health conditions studied

1

Description of health condition studied

Pemphigus Vulgaris

ICD-10 code

L10.0

ICD-10 code description

Diseases of the skin and subcutaneous tissue

2

Description of health condition studied

Pemphigus foliaceus

ICD-10 code

L10.2

ICD-10 code description

Diseases of the skin and subcutaneous tissue

Primary outcomes

1

Description

IgG1: Measuring the amount of these factors in order to evaluate the role of metformin in the improvement of pemphigus.

Timepoint

Before the intervention (at the beginning of the study) and after the intervention (three months after receiving metformin)

Method of measurement

Immunological ELISA kits

2

Description

IgG4: Measuring the amount of these factors in order to evaluate the role of metformin in the improvement of pemphigus.

Timepoint

Before the intervention (at the beginning of the study) and after the intervention (three months after receiving metformin)

Method of measurement

Immunological ELISA kits

3

Description

NFkB: Measuring the amount of these factors in order to evaluate the role of metformin in the improvement of pemphigus

Timepoint

Before the intervention (at the beginning of the study) and after the intervention (three months after receiving metformin)

Method of measurement

Immunological ELISA kits

4

Description

TNFa: Measuring the amount of these factors in order to evaluate the role of metformin in the improvement of pemphigus

Timepoint

Before the intervention (at the beginning of the study) and after the intervention (three months after receiving metformin)

Method of measurement

Immunological ELISA kits

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Metformin HEXAL (Raha-Isfahan Pharmaceutical Company) receiving a dose of 2000 mg / day, divided into 1000 mg every 12 hours for three months.

Category

Treatment - Drugs

2

Description

Control group: Metformin placebo receptor at a dose of 2000 mg / day, divided in divided doses of 1000 mg every 12 hours, for three months

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Mazandaran University of Medical Sciences

Full name of responsible person

Dr Gholamreza Houshmand

Street address

Department of Physiology and Pharmacology, Faculty of Medicine, Mazandaran University of Medical Sciences, Khazar Square, Khazar Blvd (18 km), Sari, Mazandaran, Iran

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Sari

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Email

g.houshmand@mazums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Dr Majid Saeedi

Street address

Research Deputy Center, Moalem Square, Sari, Mazandaran, Iran

City

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Mazandaran

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4847191971

Phone

+98 11 3354 3081

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majsaeedi@yahoo.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Sari University of Medical Sciences

Proportion provided by this source

50

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

Mazandaran University of Medical Sciences

Full name of responsible person

Dr Gholamreza Houshmand

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacology

Street address

Physiology and Pharmacology Department,, Faculty of
Medicine, Mazandaran University of Medical Sciences,
Khazar Square, Khazar Blvd (18 km), Sari,
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Person responsible for scientific inquiries

Contact

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Dr Gholamreza Houshmand

Position

Assistant Professor

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Other areas of specialty/work

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Person responsible for updating data

Contact

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Mazandaran University of Medical Sciences

Full name of responsible person

Dr Gholamreza Houshmand

Position

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Latest degree

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Email

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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

Qualitative variables such as age and sex, the decrease
of symptoms and clinical manifestation of Pemphigus
vulgaris and laboratory parameters: IgG1,4, TNFa, NFkB

When the data will become available and for how long

After the completion of the clinical trial and after the
publication of the article

To whom data/document is available

Researchers working in academia

Under which criteria data/document could be used

In order to study more widely and to help improve
patients with pemphigus vulgaris

From where data/document is obtainable

Department of Physiology and Pharmacology, Faculty of
Medicine, Mazandaran University of Medical Sciences,
Khazar Square, Khazar Blvd (18 km), Sari, Mazandaran,
Iran

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

A written request should be sent to the respondent's
email address, and if agreed, appointment time will be
determined.

Comments