Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Evaluation of therapeutic effect of prednisolone + dapson with prednisolone+imurane in pemphigus vulgaris treatment

Protocol summary

Summary

The aim of this study is: Evaluation of therapeutic effect of prednisolone + dapson with prednisolone+imurane in pemphigus vulgaris treatment. This study is a randomized clinical trial. Population of patients with pemphigus vulgaris visit in, a dermatology clinic of Sina hospital or Sheikh Alrayys clinic, Tabriz, Iran. Inclusion criterion: patients with pemphigus vulgaris, that their disease was detected by the clinical or pathological evidence of initial tests with pemphigus vulgaris. Exclusion criterion: patients who were G6PDD. Thirty patients were selected and randomly divided into two groups; First group treatment with prednisolone + imurane and the second group treatment with prednisolone + dapson. The study has begun from 2011/12/22. The patients for eleven months and at weeks zero, one, two, three, and four, two months later, three months later, five months later, seven months later, nine months later and eleven months later of treatment, are evaluated for recovery and complications the patient has been taking a careful history and physical examination as well as the series of experiments, two groups were compared.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201307133566N2**
Registration date: **2013-08-03, 1392/05/12**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2013-08-03, 1392/05/12

Registrant information

Name

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Name of organization / entity

Tabriz University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Tabriz university of medical sciences

Expected recruitment start date

2012-09-19, 1391/06/29

Expected recruitment end date

2013-08-20, 1392/05/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of therapeutic effect of prednisolone + dapson with prednisolone+imurane in pemphigus vulgaris treatment

Public title

Effect of dapson in treatment of pemphigus vulgaris

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criterion: patients with pemphigus vulgaris, that their disease was detected by the clinical or pathological evidence of initial tests with pemphigus vulgaris. Exclusion criterion: patients who were G6PDD.

Age

No age limit

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tabriz university of medical sciences

Street address

azady avenue,golgasht avenue

City

tabriz

Postal code

iran

Approval date

2012-09-15, 1391/06/25

Ethics committee reference number

9189

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

Severity of damage

Timepoint

The patients for eleven months and at weeks zero, one, two, three, and four, two months later, three months later, fiv months later e, seven months later, nine months later and eleven months later of treatment follow up

Method of measurement

Physical examination

Secondary outcomes

1

Description

Lipid profile

Timepoint

The patients for eleven months and at weeks zero, one, two, three, and four, two months later, three months later, fiv months later e, seven months later, nine months later and eleven months later of treatment follow up

Method of measurement

Lab tests

2

Description

HTN

Timepoint

the patients for eleven months and at weeks zero, one, two, three, and four, two months later, three months later, fiv months later e, seven months later, nine months later and eleven months later of treatment follow up

Method of measurement

lab

3

Description

Liver function test

Timepoint

The patients for eleven months and at weeks zero, one, two, three, and four, two months later, three months later, fiv months later e, seven months later, nine months later and eleven months later of treatment follow up

Method of measurement

Lab tests

Intervention groups

1

Description

control: treatment by prednisolone+imurane prednisolone 1-2mg/kg/day imurane:2-3mg/kg/day

Category

Treatment - Drugs

2

Description

Interventionaris treatment by prednisolone + dapson prednisolone 1-2mg/kg /day dapson100-200mg/day

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Dermatology cilinic of Sina hospital

Full name of responsible person

Dr. Azimi Dermatologist

Street address

sina hospital Azadi Avenue

City

Tabriz

2

Recruitment center

Name of recruitment center

Sheikh Alrayys chinic

Full name of responsible person

Dr. Azimi dermatologist

Street address

Azadi avenue

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz university of medical sciences, assistance research

Full name of responsible person

Dr.meshkini

Street address

golgasht avenue, azady avenu tabriz

City

Tabriz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tabriz university of medical sciences, assistance research

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

Tabriz university of medical sciences

Full name of responsible person

Dr. Hamide Azimi

Position

Dermatologist

Other areas of specialty/work

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Web page address

Person responsible for updating data

Contact

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