

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

comparison between the efficacy of intralesional rituximab and intralesional triamcinolone in the treatment of patients with refractory pemphigus vulgaris

Protocol summary

Study aim

Pemphigus Vulgaris (PV) is an autoimmune vesiculobullos disease characterized by autoantibody against cellular adhesion molecules. The mainstay of treatment is corticosteroid therapy, but sometimes there is resistance to corticosteroids or dependency to them which is associated with many side effects. Thus attempts to find other more safe and effective options for treating resistant patients are to be continued. Our purpose is to evaluate the efficacy of this modality versus another similar modality.

Design

blinded randomized clinical trial with a parallel group design on 21 patients, enrolled between October 2017 and November 2018, and followed for six months.

Settings and conduct

Study was done on the patients coming to the dermatology clinic of Alzahra hospital in Isfahan. At the first visit after initial measurements drugs were injected and patients come back after one months, then measurements were done again and drugs were reinjected. Then patient were visited monthly for another 4 months. Patients and persons who inject the drug were blinded.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1-Lack of responses to oral immunosuppressive treatment after 4-month 2-Non-infective lesions 3-The nonexistence of rituximab contraindication Excluding criteria: Allergic reaction and infection after rituximab injection

Intervention groups

Lesions treated with intralesional rituximab Lesions treated with intralesional triamcinolone

Main outcome variables

Percentage of changes in size of the lesions PVLS Score VAS Epithelialization Score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181224042105N1**

Registration date: **2019-01-01, 1397/10/11**

Registration timing: **retrospective**

Last update: **2019-01-01, 1397/10/11**

Update count: **0**

Registration date

2019-01-01, 1397/10/11

Registrant information

Name

Farzaneh Danesh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3264 3327

Email address

fdanesh2005@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-11-22, 1396/09/01

Expected recruitment end date

2018-11-22, 1397/09/01

Actual recruitment start date

2017-11-25, 1396/09/04

Actual recruitment end date

2018-11-21, 1397/08/30

Trial completion date

2018-11-21, 1397/08/30

Scientific title

comparison between the efficacy of intralesional rituximab and intralesional triamcinolone in the treatment of patients with refractory pemphigus vulgaris

Public title

intralesional rituximab in pemphigus vulgaris

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with refractory lesions of pemphigus vulgaris in the scalp and oral cavity after 4 months of systemic therapy No contraindication for rituximab

Exclusion criteria:

Any contraindication for rituximab

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **20**

More than 1 sample in each individual

Number of samples in each individual: **2**

Two lesions with same size and in the same anatomic area(both on the scalp or in the oral cavity) from each patient will be selected.

Actual sample size reached: **21**

More than 1 sample in each individual

Actual sample size in each individual: **2**

Two lesions with same size and in the same anatomic area(both on the scalp or in the oral cavity) from each patient were selected.

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization has been used with individual unit. It means from each patient we select two lesions with same properties (size and anatomic location) and after coin tossing we inject rituximab in one lesion and triamcinolone in another one. But the patient and person who injects the drug do not know each lesion is treated with which drug.

Blinding (investigator's opinion)

Double blinded

Blinding description

The patient and person who injects the drug do not know each lesion is treated with which drug.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University of Medical Science

Street address

No.1/61, Abolhasan Esfahani Ave, Moshtagh Blv.

City

Isfahan

Province

Isfahan

Postal code

8157637383

Approval date

2017-11-22, 1396/09/01

Ethics committee reference number

396599

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

Percentage of size variation in pemphigus lesions

Timepoint

Measurement of size of the lesions on day 1 and 30 and then month 6.

Method of measurement

Ruler and medical thermometer

Secondary outcomes

1

Description

Visual Analogue Scale

Timepoint

day 0 and 30 and then month 6.

Method of measurement

Asking from patient

Intervention groups

1

Description

Intervention group 1: 1cc intralesional ritumab10 mg/ml will be injected in 21 lesions and after one month will be repeated.

Category

Treatment - Drugs

2

Description

Intervention group 1: 1cc intralesional triamcinolone10 mg/ml will be injected in 21 lesions and after one month will be repeated.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra hospital

Full name of responsible person

Farzaneh Danesh

Street address

Dermatology Department, Alzahra hospital, Sofe street, Isfahan, Iran.

City

Isfahan

Province

Isfahan

Postal code

8174645731

Phone

+98 31 3669 5414

Email

fdanesh2055@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Farzaneh Danesh

Street address

Vice Chancellor for Research, Isfahan University Of Medical Science, Hezarjarib Street, Isfahan, Iran

City

Isfahan

Province

Isfahan

Postal code

8174645731

Phone

+98 31 3669 5414

Email

fdanesh2005@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Farzaneh Danesh

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Dermatology

Street address

No.1/61, Abolhasan Esfahani St, Moshtagh Blv.

City

Isfahan

Province

Isfahan

Postal code

8157637383

Phone

+98 31 3264 3327

Email

fdanesh2005@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Farzaneh Danesh

Position

Resident of Dermatology

Latest degree

Medical doctor

Other areas of specialty/work

Dermatology

Street address

No.1/61, Abolhasan Esfahani St, Moshtagh Blv.

City

Isfahan

Province

Isfahan

Postal code

8157637383

Phone

+98 31 3264 3327

Email

fdanesh2005@gmail.com

Person responsible for updating data**Contact****Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

Farzaneh Danesh

Position

Resident of Dermatology

Latest degree

Medical doctor

Other areas of specialty/work

Dermatology

Street address

No.1/61, Abolhasan Esfahani St, Moshtagh Blv.

City

Isfahan

Province

Isfahan

Postal code

8157637383

Phone

+98 31 3264 3327

Email

Fdanesh2005@gmail.com

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

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available