Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 mounths.

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 mounths, then measurements were done again and drugs were reinjected. Then patient were visited mounthly for another 4 mounths. Patients and pesons 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 mounths 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 benn 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 thedrug do not know each lesion is treated with which drug.
Blinding (investigator's opinion)
Double blinded
Blinding description
The patient and person who injects thedrug 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
Isfehan
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 mounth6.
Method of measurement
Ruler and medical thermometer

Secondary outcomes

1

Description
Visual Analogue Scale
Timepoint
day 0 and 30 and then mounth6.
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
Isfehan
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
Isfehan
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
Isfehan
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
Isfehan
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
Isfehan
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