Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

systemic administration and intralesional injection of rituximab in patients with pemphigus vulgaris with oral lesions

Protocol summary

Study aim
Comparing the success rate of systemic administration and intralesional injection of rituximab in patients with pemphigus vulgaris with oral lesions.

Design
A parallel-group, unblinded, randomized, phase 2 clinical trial of 20 patients. A table of random numbers is used for randomization.

Settings and conduct
This study is conducted on 20 patients over 18 years old with pemphigus vulgaris with oral lesions in Tabriz Sinai Hospital. Subjects will be randomly assigned 10 people to the systemic administration group and 10 people to the systemic administration group with intralesional administration (10 mg/ml in two doses with an interval of 15 days). The variables studied before the study, day 15th, 33 months after injection will be checked and recorded. A complete response to treatment is considered a condition when the pemphigus vulgaris lesion severity score for mucosal lesions reaches zero. Patient satisfaction are also assessed with a visual analog scale.

Participants/Inclusion and exclusion criteria
Its target population is 20 patients over 18 years of age with pemphigus vulgaris with oral lesions who did not respond to corticosteroids and rituximab was started for them. Pregnant and lactating people, allergic to rituximab, coagulation, cardiovascular diseases, malignancy and hepatitis are excluded from the study.

Intervention groups
Systemic administration intervention where a 50 cc vial of rituximab containing 500 mg/50 ml is injected intravenously to patients four times with an interval of one week in a period of one month. Intervention of intralesional injection of Rituximab with a dose of 10 mg/ml into the lesion twice with an interval of 15 days.

Main outcome variables
severity of pemphigus vulgaris lesion; Patient satisfaction

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20240604062002N1**
Registration date: **2024-07-11, 1403/04/21**
Registration timing: **prospective**

Last update: **2024-07-11, 1403/04/21**
Update count: **0**

Registration date
2024-07-11, 1403/04/21

Registrant information

Name
Faegheh Sheikhalizadeh Noubar

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-07-22, 1403/05/01

Expected recruitment end date
2024-10-22, 1403/08/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

systemic administration and intralesional injection of rituximab in patients with pemphigus vulgaris with oral lesions

Public title
effects of rituximab in patients with pemphigus vulgaris with oral lesions
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
People over 18 years old with pemphigus vulgaris with oral lesions Patients who have not had a therapeutic response to corticosteroid administration Patients for whom rituximab has been started
Exclusion criteria:
Pregnancy and breastfeeding People who have coagulation problems Patients with infection at the site of the lesion Rituximab contraindications include hypersensitivity to it or its components Having hepatitis B Having cardiovascular diseases Having malignant diseases
Age
From **18 years** old to **80 years** old
Gender
Both

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **20**
Randomization (investigator's opinion)
Randomized
Randomization description
A simple randomization will be carried out on an individual basis by RandList software. The selection of patients will be based on sealed envelopes that be written A and B inside them. 20 envelopes will be prepared in two groups. After entering the clinic and before the visit, patients will receive the envelope from the secretary and hand it over to the physician.
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
Ethics Committee of Tabriz University of Medical Sciences
Street address
Third floor, Central Building No.2, Tabriz University of Medical Sciences, Gholgasht street
City
Tabriz
Province
East Azarbaijan
Postal code
5163639888
Approval date
2024-06-24, 1403/04/04
Ethics committee reference number
IR.TBZMED.REC.1403.254

Health conditions studied

1

Description of health condition studied
Pemphigus vulgaris lesion
ICD-10 code
L10.0
ICD-10 code description
Pemphigus vulgaris

Primary outcomes

1

Description
Severity of pemphigus vulgaris lesion
Timepoint
Before the study, on the 15th day, 33 months after the injection
Method of measurement
PVLSS: Pemphigus Vulgaris Lesion Severity Score

2

Description
Patient satisfaction
Timepoint
Before the study, on the 15th day, 33 months after the injection
Method of measurement
VAS: Visual analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: First intervention: Systemic administration intervention where a 50 cc vial of rituximab containing 500 mg/50 ml is injected intravenously to patients four times with an interval of one week in a period of one month.

Category
Treatment - Drugs

2

Description
Intervention group: Second intervention: Systemic administration along with intralesional administration of 10 mg/ml on two occasions with an interval of 15 days.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Dermatology Department of Sina Hospital, Tabriz University of Medical Sciences.
Full name of responsible person
Dr. Fayegh Sheikh Alizade Nobar
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Dr. Parviz Shahabi
Street address
Vice Chancellor for Research, Central Building of Tabriz University of Medical Sciences, Daneshgah Square
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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
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
Tabriz University of Medical Sciences
Full name of responsible person
Dr. Faegheh Sheikhalizadeh Nobar
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Dermatology
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Person responsible for updating data

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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
No - There is not 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
The study data are classified and coded so that the names of the individuals cannot be identified. Access to all the study data will be possible except for the identifying information of the individuals.

When the data will become available and for how long
Access to study data after publication of the result is available in the journal

To whom data/document is available
Anyone interested in using the data can access the study data

Under which criteria data/document could be used
Study data can be used for comparison with other results

From where data/document is obtainable
Refer to the study's scientific or public accountability person for data.

What processes are involved for a request to access data/document
The request will be sent by email to person responsible for scientific or public inquiries.

Comments