Clinical Trial Protocol
Iranian Registry of Clinical Trials

12 Jun 2026

Evaluation of the efficasy of intralesional rituximab injection for remision of recalcitrant lesions in the patients with pemphigus vulgaris.

Protocol summary

Study aim

Evaluation of efficacy of intralesional rituximab injection in the treatment of recalcitrant mucocutaneous lesions in patients with pemphigus vulgaris

Design

Since pemphigus is not a common disease and there is no large-scale controlled clinical trial on treatment regimens, only one study found that rituximab was studied in only 3 patients. Therefore, the primary study should be based on the pilot and on 15 patients will be treated.

Settings and conduct

Patients on the first day and on Day 15 will receive rituximab at a dose of 5 mg / cm2 of the drug (i.e., per centimeter of the lesion of 0.5 cc) intra-lesion. Before injection of rituximab, intravenous injections of hydrocortisone 100 mg and chlorpheniramine and one dose of acetaminophen 500 mg tablet will be given. Patients will be followed for 6 months.

Participants/Inclusion and exclusion criteria

A total of 15 patients with pemphigus vulgaris referring to the Dermatology Clinic of the Razi Hospital, which have inclusion criterias, will be studied. ■ Inclusion Criteria: 1. Clinically , histologically and immunologically approved pemphigus vulgaris. 2. Mucosal or skin involvement with totally maximum diameter of 6 cm or 20 cm2 that are resistant to common immunosuppressive treatment. 3. Inadequate response after three intralesional injection of triamcinolone acetonide or use of potent topical steroids for 2 months 4. Lack of active lesion 5. Steroid dose of 20 mg or less. ■ Exclusion criteria: 1. Contraindication for the treatment of rituximab . 2. Receiving intravenous rituximab within 6 months before the start of the study.

Intervention groups

Patients with pemphigus vulgaris who have recalciterant mucocutaneous lesions.

Main outcome variables

Anti desmogeline1 - Anti desmogeline 3 - CD4 cell count - CD19 cell count and size of lesions.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141209020250N3**
Registration date: **2018-06-19, 1397/03/29**
Registration timing: **prospective**

Last update: **2018-06-19, 1397/03/29**
Update count: **0**

Registration date

2018-06-19, 1397/03/29

Registrant information

Name

Narges Ghandi

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 5561 8989

Email address

nghandi@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-08-23, 1397/06/01

Expected recruitment end date

2019-08-23, 1398/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Evaluation of the efficasy of intralesional rituximab injection for remision of recalcitrant lesions in the patients with pemphigus vulgaris.

Public title
Effect of intralesional injection of rituximab in recalcitrant pemphigus lesions.

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
suffering from pemphigus vulrais, confirmed by clinical, histoligical and immunological criteria. Skin or mucosal lesions with maximum diameter of 6 cm or 20 cm2 which are recalcitrant (means continued development of new lesions, continued extension of old lesions, or failure of established lesions to begin to heal despite 3 weeks of therapy on 1.5 mg/kg/d of prednisone equivalent with or without any of the following agents: cyclophosphamide 2 mg/kg/d for 12 weeks; azathioprine 2.5 mg/kg/d for12 weeks (if thiopurine s-methyltransferase level is normal); methotrexate 20 mg/wk for 12 weeks; or mycophenolate mofetil 3 g/d for 12 weeks.). Insufficient response to three times intralesional injection of triamcinolone acetonide or topical super potent corticosteroid for at least 1 month. no new lesion in recent 12 weeks. no cardiac or infectious contraindication to rituximab. oral steroid usage of <= 20 mg/d.

Exclusion criteria:
Patients with active lesions (expansion of previous old lesions or new lesions in recent 12 weeks). Contraindications to rituximab (including hepatitis B, hepatitis C, progressive neurologic disease, angina, arrhythmia, herpes virus infection, CMV infection, acute pneumonia, renal diseases, lactation, hyperphosphatemia, hypocalcemia, hyperkalemia, anemia, low platelet or leukocyte count. Injection of intravenous rituximab in recent 6 months.

Age
No age limit

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **20**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Single

Other design features
quazi-experimantal

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Tehran University of Medical Sciences Ethics committee

Street address
Tehran University of Medical Sciences, Office of Vice Chancellor for Research and Technology, 6th floor, Ghods Street, Keshavarz Boulevard

City
Tehran

Province
Tehran

Postal code
1417653761

Approval date
2018-03-07, 1396/12/16

Ethics committee reference number
IR.TUMS.VCR.REC.1396.4747

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
Anti desmogline 1

Timepoint
baseline , 3 months , 6 months later

Method of measurement
blood sampling

2

Description
Anti desmogline 3

Timepoint
baseline , 3 months , 6 months

Method of measurement
blood sampling

3

Description
CD4 cell count
Timepoint
baseline , 15 day and 1 month later
Method of measurement
blood sampling

4

Description
CD19 cell count
Timepoint
baseline , 15 day and 1 month later
Method of measurement
blood sampling

Secondary outcomes

1

Description
disease severity
Timepoint
before intervention and 1, 3, 6 months after intervention
Method of measurement
Pemphigus Disease Area Index (PDAI)

2

Description
patient satisfaction
Timepoint
baseline, 1 month , 3 month , 6 month later
Method of measurement
Visual analyze scale

3

Description
quality of life
Timepoint
baseline, 1 month , 3 month , 6 month later
Method of measurement
pemphigus quality of life questioner

4

Description
size of lesion
Timepoint
baseline, 15 days , 1 month , 3 month , 6 month later
Method of measurement
ruler

Intervention groups

1

Description
Intervention group: for 15 patient with mucocutaneous recalcitrant lesion of pemphigus vulgaris , we will prescribe intralesional injection of rituximab with dose of 5 mg/cm2 (0/5 cc per 1 cm2 of lesion) , we will take patients stat dose of hydrocortisone 100 mg , chlorpheniramin and acetaminophen 500 mg before of injection and we will follow them for 6 months.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Razi Hospital
Full name of responsible person
Narges Ghandi
Street address
District 12 , vahdat eslami square
City
Tehran
Province
Tehran
Postal code
1199663911
Phone
+98 21 5563 0174
Email
nghandi@tums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Doctor Seyyed Ahmad Rezayi
Street address
sixth floor, Vice chancellor of research and technology, central organization of Tehran University of Medical Sciences, at the corner of Qods street, Keshavarz boulevard
City
Tehran
Province
Tehran
Postal code
1417653761
Phone
+98 21 8163 3698
Fax
+98 21 8163 3623
Email
rmo@tums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source

Tehran 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
Tehran University of Medical Sciences

Full name of responsible person
EBRAHIM MAZLOOM

Position
RESIDENT

Latest degree
Medical doctor

Other areas of specialty/work
Dermatology

Street address
No 1, bakhshandegan Avenue, Valiasr BLV,Tehran

City
Tehran

Province
Tehran

Postal code
1516744163

Phone
+98 21 8820 8156

Email
hanymazloom@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Narges Ghandi

Position
Associate professor

Latest degree
Specialist

Other areas of specialty/work
Dermatology

Street address
District 12, vahdate eslami square, Razi hospital

City
Tehran

Province
Tehran

Postal code
1199663911

Phone
+98 21 5563 0553

Email
nghandi@tums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Ebrahim Mazloom

Position
Resident

Latest degree
Medical doctor

Other areas of specialty/work
Dermatology

Street address
No 1, bakhshandegan avenue, valiasr BLV,Tehran

City
Tehran

Province
Tehran

Postal code
1516744163

Phone
+98 21 8820 8156

Email
hanymazloom@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is 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

Title and more details about the data/document
All data including age, sex, duration of illness, drugs used by the patient, amount and duration of taking corticosteroid and immunosuppressive, history of rituximab injection, duration of previous injection of rituximab, complications of intra-lesion injection of rituximab, severity of complications, severity of disease and satisfaction and score of Quality of life, The changes in desmagolin levels 1 and 3, and changes in levels of CD4 and CD19 cell count will be released.

When the data will become available and for how long

As soon as completion of the study and analysis of the data, the results will be available to the researchers.

To whom data/document is available

All investigators , students , doctors and, in general, people working in the field of autoimmune bullous disorders.

Under which criteria data/document could be used

To achieve a safe and low-cost effective treatment protocol for patients with pemphigus vulgaris who suffer from recalcitrant mucosal lesions.

From where data/document is obtainable

Dept. of Research and Technology of Tehran University of Medical Sciences and Autoimmune bullous Disorders Research Center and Iranian Record of Clinical Trial website

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

Login to Autoimmune Bullous Disorders Research Center and Iranian Record of clinical trial Center

Comments