

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Aug 2026

Evaluation of the efficacy of seasonal influenza vaccine in pemphigus Patients

Protocol summary

Study aim

The effectiveness of seasonal influenza vaccine in pemphigus patients

Design

Each of the patients will receive their unique code after entering the study, then accidentally placed in one of two groups A or B, two groups are A: a group that underwent flu vaccine injection and B :a group that has been present as a control study. Each of the patients is monitored and followed for 12 months, and every 3 months during the patients visit DSMOGLEIN1 & 3 is checked.PDAI factors are also recorded for patients.

Settings and conduct

Each of the patients will receive their unique code after entering the study, then accidentally placed in one of two groups A or B, two groups are A: A group that underwent A flu vaccine injection and B : A group that has been present as a control study. Each of the patients is monitored and followed for 12 months, and every 3 months during the patients visit DSMOGLEIN1 & 3 is checked.PDAI factors are also recorded for patients. .

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age over 18 and less than 65 years
History of receiving the Rituximab 6 month ago In the course of disease improvement Be treated with the least dosage of immunosuppressant drugs Exclusion Criteria:
History of sensitivity to vaccines. Egg sensitivity.
Mushroom Allergy Patient's lack of consent

Intervention groups

Intervention group: patients receiving seasonal influenza vaccine Control group: Pemfigus patients undergo routine routine control

Main outcome variables

The efficacy of influenza vaccine in pemphigus patients

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191022045185N1**

Registration date: **2020-01-20, 1398/10/30**

Registration timing: **registered_while_recruiting**

Last update: **2020-01-20, 1398/10/30**

Update count: **0**

Registration date

2020-01-20, 1398/10/30

Registrant information

Name

Maryam Hadi chegeni

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6119 2656

Email address

maryamhadi86@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-10-21, 1398/07/29

Expected recruitment end date

2021-09-20, 1400/06/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the efficacy of seasonal influenza vaccine in pemphigus Patients

Public title

Evaluating the efficacy of seasonal influenza vaccine in pemphigus Patients

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

pemphigus Patients Patients treated with minimal dose therapy (disease in control phase) A history of receiving a biological drug more than six months ago

Exclusion criteria:

The patient is in the active phase of the disease Be treated with high doses of the drug received a biological drug six months ago

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization of individual randomization units using g power statistical software

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 Tehran University of Medical Sciences

Street address

Floor 13, Block A, Ministry of Health & Medical Education Headquarters, Between Zarafashan & South Falamak, Qods Town, Tehran, Iran.

City

tehran

Province

Tehran

Postal code

1417653761

Approval date

2019-12-23, 1398/10/02

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1398.675

Health conditions studied

1

Description of health condition studied

Pemphigus disease

ICD-10 code

L10.0

ICD-10 code description

Pemphigus vulgaris

Primary outcomes

1

Description

Evaluation of the effectiveness of seasonal influenza vaccine in relapse rate of pemphigus in patients under control of pemphigus

Timepoint

before and every three month

Method of measurement

PDAl ,Dsg1/3

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Pemfigus-controlled patients receiving minimal dose therapy receive one injection for seasonal influenza vaccine patients.

Category

N/A

2

Description

Control group: Pemphigus-controlled patients undergoing minimal dose therapy receiving routine care

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Razi hospital

Full name of responsible person

maryam hadi chegeni

Street address

razi hospital, vahdat eslami ave

City

tehran

Province
Tehran
Postal code
1199663911
Phone
+98 21 5569 6708
Fax
+98 21 5562 0300
Email
razihospital@sina.tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
hamidreza mahmoody
Street address
University of Tehran Poorsina Street
City
tehran
Province
Tehran
Postal code
1417613151
Phone
+98 21 4293 0000
Email
tums_edu@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
hamidreza mahmoody
Position
Assistant Professor
Latest degree
Specialist

Other areas of specialty/work

Dermatology

Street address

vahdat eslami ave,

City

tehran

Province

Tehran

Postal code

1199663911

Phone

+98 21 5569 6708

Email

hr_mahmoody@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
hamidreza mahmoody
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
Dermatology
Street address
vahdat eslami ave,
City
tehran
Province
Tehran
Postal code
11996633911
Phone
+98 21 5569 6708
Email
hr_mahmoody@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
maryam hadi chegeni
Position
resident
Latest degree
Medical doctor
Other areas of specialty/work
Dermatology
Street address
vahdat eslami ave,
City
tehran
Province
Tehran
Postal code

1199663911

Phone

+98 21 5569 6708

Email

maryamhadi86@gmail.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

Not applicable

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

Not applicable

Title and more details about the data/document

All data is shareable.

When the data will become available and for how long

After the end of study

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

For research and study

From where data/document is obtainable

First responsible of study

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

Send a request to a responsible

Comments