Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Jul 2026

Efficacy of Botulinum Toxin A Injection for Raynaud's Phenomenon and digital ulcers in patients with systemic sclerosis (scleroderma)

Protocol summary

Study aim

The effect of local botulinum toxin A injection on the improvement of symptoms of Raynaud's phenomenon and digital ulcers in systemic sclerosis

Design

Thirty patients will be included in the study. Non-dominant hands of patients will be used as intervention group and the dominant hands of patients as control group.

Settings and conduct

Before the intervention, patients' demographic information and the results of physical examinations will be recorded. Then Quick DASH, pain score (VAS) and Raynaud's condition score (RCS) questionnaires will be completed. Then, 50 units of botulinum toxin will be mixed with 2.5 cc of normal saline. The injection sites are: second-forth interdigital webs (each one 10 units)، base of thumb (10 units) , second and fifth fingers (each 5 units). In the other hand, only normal saline will be injected in the same way. At end of months 1 and 4, patients will be reassessed.

Participants/Inclusion and exclusion criteria

Inclusion criteria: scleroderma diagnosis based on the American College of Rheumatology (ACR) and the European League Against Rheumatism (EULAR), age>18 years, bilateral Raynaud's phenomenon with an intensity of greater than 50 according to the Raynaud's condition score (RCS), pain intensity greater than 5 based on visual analog scale (VAS), dysfunction of the arm, shoulder and hand more than 50 according to the Quick Disabilities of the Arm, Shoulder and Hand (DASH) Questionnaire. Exclusion criteria: Active infection in the hands, history of any botulinum toxin allergy, history of upper extremity vascular surgery, history of sympathectomy, pregnancy, breast feeding

Intervention groups

In the non-dominant hand, botulinum toxin A and into the dominant hand of each patient (as control), normal saline will be injected.

Main outcome variables

Symptoms of Raynauds's phenomenon; pain intensity; dysfunction of the arm, shoulder and hand

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20081202001479N7**
Registration date: **2018-12-29, 1397/10/08**
Registration timing: **prospective**

Last update: **2018-12-29, 1397/10/08**
Update count: **0**

Registration date

2018-12-29, 1397/10/08

Registrant information

Name

Mohammadhassan Jokar

Name of organization / entity

Mashhad University of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 51 1859 8818

Email address

jokarmh@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-01-10, 1397/10/20

Expected recruitment end date

2019-04-09, 1398/01/20

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Efficacy of Botulinum Toxin A Injection for Raynaud's Phenomenon and digital ulcers in patients with systemic sclerosis (scleroderma)

Public title
Botox in the treatment of Raynaud's phenomenon in scleroderma
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Scleroderma diagnosis based on the American College of Rheumatology (ACR) and the European League Against Rheumatism (EULAR) criteria age>18 years Bilateral Raynaud's phenomenon with an intensity greater than 50 according to the Raynaud's condition score (RCS) questionnaire Dysfunction of the arm and shoulder and arm more than 50 according to the Quick Disabilities of the Arm, Shoulder and Hand (DASH) questionnaire Pain intensity greater than 5 based on visual analog scale (VAS)
Exclusion criteria:
Active infection in any of the hands History of any botulinum toxin allergy History of upper extremity vascular surgery History of sympathectomy Pregnancy Breast feeding
Age
From **18 years** old
Gender
Both

Phase
4
Groups that have been masked
No information
Sample size
Target sample size: **30**
More than 1 sample in each individual
Number of samples in each individual: **2**
In this study, we will inject botulinum toxin A into the non-dominant hands and normal saline (as placebo) into the dominant hands of patients.
Randomization (investigator's opinion)
Not randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Mashhad University for Medical Science
Street address
Mashhad University for Medical Science, Daneshgah street
City
Mashhad
Province
Razavi Khorasan
Postal code
1394491388
Approval date
2018-10-31, 1397/08/09
Ethics committee reference number
IR.MUMS.MEDICAL.REC.1397.334

Health conditions studied

1

Description of health condition studied
systemic sclerosis (scleroderma)
ICD-10 code
M34
ICD-10 code description
Systemic sclerosis [scleroderma]

Primary outcomes

1

Description
Raynaud's phenomenon symptoms
Timepoint
At the beginning of study and end of months 1 and 4
Method of measurement
Raynaud's phenomenon condition score Questionnaire

Secondary outcomes

1

Description
Ulcers of fingers
Timepoint
At the beginning and end of months 1 and 4
Method of measurement
Counting the number of ulcers and measuring the diameter of the ulcers

2

Description
Disabilities of the Arm, Shoulder and Hand
Timepoint

At the beginning of study and end of months 1 and 4

Method of measurement

Disabilities of the Arm, Shoulder and Hand Score(QuickDash)

Intervention groups

1

Description

Control group: Dominant hands of the patients. Normal saline (total volume 2.5 cc) with insulin syringe will be injected into the following sites: second-forth interdigital webs، base of thumb, second and fifth fingers. Injection will only be done once.

Category

Placebo

2

Description

Intervention group: Non-dominant hands of patients. Fifty units of botulinum toxin (DYSPORT®, IPSEN, UK) will be mixed with 2.5 cc of normal saline. The injection sites are: second-forth interdigital webs (each one 10 units)، base of thumb (10 units) , second and fifth fingers (each 5 units). Injection will only be done once.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital, Mashhad

Full name of responsible person

Dr Mohammadhassan Jokar

Street address

Chamran street

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913316

Phone

+98 51 3859 8818

Email

jokarmh@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaghodi

Street address

Daneshgah street, Vice-Chancellor for Research of Mashhad University of Medical Sciences

City

Mashhad

Province

Razavi Khorasan

Postal code

1394491388

Phone

+98 51 3841 2081

Email

Tafaghodim@mums.ac.ir

Grant name

Grant of Research Project of Vice-Chancellor for Research of Mashhad University of Medical Sciences

Grant code / Reference number

961794

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

No

Title of funding source

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Mohammadhassan Jokar

Position

Associated professor

Latest degree

Subspecialist

Other areas of specialty/work

Internal Medicine

Street address

Chamran street

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913316

Phone

+98 51 3859 8818

Email

jokarmh@mums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Mohammad Hassan Jokar

Position
Associated professor

Latest degree
Subspecialist

Other areas of specialty/work
Internal Medicine

Street address
Chamran St. Imam Reza Hospital

City
Mashhad

Province
Razavi Khorasan

Postal code
9137913316

Phone
+98 51 3859 8818

Email
jokarmh@mums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Mohammad Hassan Jokar

Position
MD, Rheumatologist, Associated Professor

Latest degree
Subspecialist

Other areas of specialty/work
Internal Medicine

Street address
Internal medicine ward, Imam Reza Hospital, Chamran street

City
Mashhad

Province
Razavi Khorasan

Postal code
9177899191

Phone
+98 51 3859 8818

Fax
+98 51 3859 8818

Email
jokarmh@mums.ac.ir

Web page address
http://my.mums.ac.ir/default.aspx

Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
There is no further information

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available