

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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-fourth 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 Raynaud'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)

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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 (DYSPORE®, 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

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Chamran street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

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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

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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