

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 Jul 2026

Assessment of the botulinum toxin type A effect on Intensified Raynauds Phenomenon in Sclerodermic patients

Protocol summary

Study aim

Assessment of botulinum toxin type A effect on Intensified Raynauds Phenomenon in Sclerodermic patients

Design

This study will be a double blind clinical trial. Eleven scleroderma patients with intensified Raynauds will be randomly assigned to receive 50 units of botulinum toxin A in one hand (intervention group) and normal saline in the other hand (placebo group).

Settings and conduct

scleroderma patients with intensified Raynauds referred to the rheumatology clinic of Imam Khomeini Hospital in Urmia will be enrolled. In one hand, 50 units of botulinum toxin A as an intervention and in the other hand normal saline will be injected. In this way, 10 units of Botox A will be injected for each of the inter-finger space of second, three and four fingers at two separate points near each finger and also for the inter-finger space between the radial surface of second finger and the ulnar surface of fifth finger, finally at both the radial and ulnar surface of thumb finger five units of Botox will be injected. totally, 50 units of Botox will be injected. The same volume of normal saline will be injected into the other hand. Patients will be followed one and two months after the injection.

Participants/Inclusion and exclusion criteria

Inclusion criteria: diagnosed scleroderma according to American college of Rheumatology criteria; Age over 18 years; severe and resistance Raynauds to oral therapy. Exclusion criteria: Myasthenia gravis disease; Pregnancy and lactation; History of vascular surgery and surgical sympathectomy; Currently use of Aminoglycosides; Presence of Active infection

Intervention groups

fifty units of botulinum toxin as intervention and normal saline.

Main outcome variables

The Raynauds activity; Number of new wounds

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200106046023N1**

Registration date: **2020-03-20, 1399/01/01**

Registration timing: **retrospective**

Last update: **2020-03-20, 1399/01/01**

Update count: **0**

Registration date

2020-03-20, 1399/01/01

Registrant information

Name

Syedmostafa Seyedmardani

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-09-23, 1397/07/01

Expected recruitment end date

2019-02-18, 1397/11/29

Actual recruitment start date

2018-09-23, 1397/07/01

Actual recruitment end date

2019-09-22, 1398/06/31

Trial completion date

2019-09-22, 1398/06/31

Scientific title

Assessment of the botulinum toxin type A effect on Intensified Raynauds Phenomenon in Sclerodermic patients

Public title

Assessment of the botulinum toxin type A effect on Intensified Raynauds Phenomenon in Sclerodermic patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with scleroderma based on ACR criteria Patients with Age over 18 years Intensified and Resistant Raynauds

Exclusion criteria:

A history of allergy to Botox History of myasthenia gravis disease Pregnancy and lactation Taking estrogen-containing pills in the last month History of vascular surgery and sympathectomy Consumption of Aminoglycoside Antibiotics The presence of active infection The presence of severe bleeding tendency

Age

From **18 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **11**

More than 1 sample in each individual

Number of samples in each individual: **1**

Right hand and left hand

Actual sample size reached: **11**

Randomization (investigator's opinion)

Randomized

Randomization description

The hands of each patients were randomly divided into intervention and control groups. In this way, based on random number table, even numbers were considered as intervention hand and odd numbers as control hand.

Blinding (investigator's opinion)

Double blinded

Blinding description

The patient, researcher and subject who evaluated the outcomes of study were unaware from intervention and placebo group.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Urmia University of Medical Sciences

Street address

No. 14000245577, Resalat street., Jahad Blvd., Urmia University of Medical Sciences., Urmia., Iran.

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Urmia

Province

West Azarbaijan

Postal code

57147-83734

Approval date

2018-09-11, 1397/06/20

Ethics committee reference number

ir.umsu.rec.1397.192

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

The Raynauds activity

Timepoint

Before intervention; one and two months after injection of botulinum toxin A

Method of measurement

The Reynolds Activity Score will be measured using a standard questionnaire consisting of 4 subsets, each rated 0-4 score.

2

Description

Number of new wounds

Timepoint

Before intervention; one and two months after injection of botulinum toxin A

Method of measurement

The number of new wounds in the fingers will be counted by clinical examination.

Secondary outcomes

1

Description

The number of fingers wounds

Timepoint

Before intervention, one and two months after injection of botulinum toxin A

Method of measurement

The number of wounds in the fingers will be counted by clinical examination.

2

Description

Pain

Timepoint

Before intervention, one and two months after injection of botulinum toxin A

Method of measurement

Visual Analogue Scale

Intervention groups

1

Description

Intervention group: Fifty units of botulinum toxin A

Category

Treatment - Other

2

Description

Control group: 50 units of normal saline

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini hospital

Full name of responsible person

Dr. SeyedMostafa SeyedMardani

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Dr. Iraj Mohebbi

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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

Oroumia 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

Oroumia University of Medical Sciences

Full name of responsible person

Dr. SeyedMostafa SeyeMardani

Position

Assistant of Rheumatology

Latest degree

Subspecialist

Other areas of specialty/work

Internal Medicine

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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

Confidentiality of patient information

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

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

The results will be published in print form.

When the data will become available and for how long

after article publishing

To whom data/document is available

Corresponding author

Under which criteria data/document could be used

An article published

From where data/document is obtainable

Corresponding author

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

Access via e-mail

Comments