Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

A comparison study of the effect of intralesional injection of botulinum toxin type A with triamcinolone acetonide in the treatment of pruritus after burns in Taleghani Hospital, Ahvaz in 1403

Protocol summary

Study aim
Effect of intralesional injection of botulinum toxin type A with triamcinolone in the treatment of pruritus after burns
Design
Parallel group, single-blind, clinical trial
Settings and conduct
In Taleghani Hospital in Ahvaz, burn patients were divided into two groups. Triamcinolone was injected for itch control in the control group, and botulinum toxin was injected for intervention group.
Participants/Inclusion and exclusion criteria
Burn patients; Pregnant and breastfeeding woman, Being allergic to botulinum toxin type A, immune deticiency, neuromuscular disease such as MS and MG.
Intervention groups
Injection of botulinum type A to the burn lesion
Main outcome variables
The level of itching, age, gender, depth of burn, location of burn.

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20240418061517N1**
Registration date: **2024-07-17, 1403/04/27**
Registration timing: **retrospective**

Last update: **2024-07-17, 1403/04/27**
Update count: **0**
Registration date
2024-07-17, 1403/04/27

Registrant information
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Shahram Goudarzi
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2024-03-26, 1403/01/07
Expected recruitment end date
2024-04-24, 1403/02/05
Actual recruitment start date
2024-03-26, 1403/01/07
Actual recruitment end date
2024-04-24, 1403/02/05
Trial completion date
2024-09-05, 1403/06/15

Scientific title
A comparison study of the effect of intralesional injection of botulinum toxin type A with triamcinolone acetonide in the treatment of pruritus after burns in Taleghani Hospital, Ahvaz in 1403

Public title
"Effect of intralesional injection of botulinum toxin type A with triamcinolone in the treatment of pruritus after burns”
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Burn
Exclusion criteria:

Pregnant and breastfeeding woman Being allergic to botulinum toxin type A Weak immune system Neuromuscular disorders such as MS and myasthenia gravis

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **60**

Actual sample size reached: **60**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

In each patient, the area with the most itching due to the burn is selected. This area is divided into two equal parts, with botulinum toxin type A injected into one part and triamcinolone acetonide injected into the other. These areas are recorded on a chart known to the physician, but the patient has no informtion about which drug is injected into which part.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ahvaz Jondishpur Univercity of Medical Science

Street address

Golestan Highway, Jondishpur Univercity of Medical Science

City

Ahvaz

Province

Khouzestan

Postal code

6135715749

Approval date

2024-02-07, 1402/11/18

Ethics committee reference number

IR.AJUMS.REC.1402.619

Health conditions studied

1

Description of health condition studied

Burn

ICD-10 code

T31

ICD-10 code description

Burns classified according to extent of body surface involved

Primary outcomes

1

Description

Amount of botolinum toxin

Timepoint

After one month

Method of measurement

Unit

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: receiving botulinum toxin type A from the manufacturer”Maspore” at the dose of 500 units, diluted with 2 ml of saline per vial, resulting in 25 units of botulinum toxin type A per 0.1 ml injected intralesionally.

Category

Treatment - Drugs

2

Description

Control group: receiving an ampoule of triamcinolone acetonide at a concentration of 10 mg/ml, injected to achieve blanching of the site. Patients are followed up for 6 months and their itching severity is assessed during visits.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Taleghani Hospital

Full name of responsible person

Dr. Hosseininejad

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Hejrat Blvd, Padadshahr

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Ahvaz 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
Ahvaz University of Medical Sciences
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Resident
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is 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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All information can be shared.

When the data will become available and for how long

Four month after publication.

To whom data/document is available

Everyone

Under which criteria data/document could be used

Treatment of burn patients.

From where data/document is obtainable

My Email address

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

As soon as possible

Comments