Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Evaluating the effectiveness of stress ball for the management of botulinum toxin injection pain in volunteers receiving Botox to eliminate hyperkinetic facial wrinkles on the upper face: a randomized self-controlled trial

Protocol summary

Study aim

The aim of the present study is to investigate whether the stress ball can reduce pain during BT injection.

Design

Before injection on one side, two stress balls are placed in both palms. Patients are asked to "squeeze the stress balls twice and count to five" and "repeat this until the end of the entire injection". Stress balls have medium hardness and are made of high quality silicone. At the same time as squeezing the stress balls, BT injection is also done. Immediately after BT injection, patients complete questionnaires that indicate the level of pain experienced. Then it is injected to the opposite side with out using the balls and the questionnaire is completed again. In half of the patients, the intervention is performed in the first injection (right side) and in the rest in the second injection (left side).

Settings and conduct

This study is conducted in dermatology clinic by the dermatologist of the team and on volunteers who come to the clinic for Botox injections.

Participants/Inclusion and exclusion criteria

(1) age above 18 years (2) Volunteers wants to correct hyperkinetic facial wrinkles through Botox injection in the upper face.

Intervention groups

To perform this investigation, patients must squeeze two stress balls in their hand during Botox injection on one side of the face.

Main outcome variables

Visual Analog Scale (VAS) questionnaire will be used to measure the pain caused by the injection.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230823059230N1**
Registration date: **2023-09-22, 1402/06/31**
Registration timing: **registered_while_recruiting**

Last update: **2023-09-22, 1402/06/31**
Update count: **0**

Registration date

2023-09-22, 1402/06/31

Registrant information

Name

Bahareh ẹbrahimi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3612 2202

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-09-11, 1402/06/20

Expected recruitment end date

2024-01-21, 1402/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the effectiveness of stress ball for the management of botulinum toxin injection pain in volunteers receiving Botox to eliminate hyperkinetic facial wrinkles on the upper face: a randomized self-controlled trial

Public title
Evaluating the effectiveness of the stress ball for the management of botulinum toxin injection pain: a randomized controlled trial
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Age over 18 years. Volunteering to correct hyperkinetic facial wrinkles by intramuscular injection of Botox in the upper face, including forehead, lateral orbital, and glabellar.
Exclusion criteria:
No history of allergy to Botox
Age
From **18 years** old
Gender
Both

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
The "intervention" is performed in half of the patients while injecting on the right side, and in the rest while the left side is being injected. To randomly select the intervention half, we write the words "right" and "left" on some cards and ask the patient to choose a card.
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
Research Ethics Committee, Faculty of Medicine, Shiraz University of Medical Sciences
Street address
School of Medicine, Imam Hossein square, Zand St., Shiraz, Iran
City
Shiraz
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۷۱۳۴۸۴۵۷۹۴
Approval date
2022-07-16, 1401/04/25
Ethics committee reference number
IR.SUMS.MED.REC.1401.201

Health conditions studied

1

Description of health condition studied
Skin Wrinkle
ICD-10 code
L98.9
ICD-10 code description
Disorder of the skin and subcutaneous tissue, unspecified

Primary outcomes

1

Description
Injection pain
Timepoint
Immediately after injection
Method of measurement
Visual Analog Scale (VAS) questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: participants were asked to squeeze stress balls in both hands during the BT injection (on one side of the face).
Category
Treatment - Devices

2

Description
Control group: the group that does nothing during BT injection (on one side of the face).
Category
Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center
Shahid Faghihi Hospital

Full name of responsible person
Mohammad Reza Namazi

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Shahid Faghihi Hospital, Imam Hossein Square, Zand St., Shiraz, Iran

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Sponsors / Funding sources

1

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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
Shiraz 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
Shiraz University of Medical Sciences

Full name of responsible person
Maryam Naseh

Position
Assistant professor

Latest degree
Ph.D.

Other areas of specialty/work
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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
Undecided - It is not yet known if there will be 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
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
Questionnaire data will be available to others without the patients' name.
When the data will become available and for how long
Immediately after the publication of the article.
To whom data/document is available
The data will be available to all concerned.
Under which criteria data/document could be used
The use of data and their analysis in meta-analysis studies is allowed.
From where data/document is obtainable
Applicants can email the correspond author (Bahareh Ebrahimi) and get the data.
What processes are involved for a request to access data/document
it is enough to explain the purpose of accessing the data and the relevant proposal and provide the resume and affiliation.
Comments