

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jul 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 ebrahimi

Name of organization / entity

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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		City	Shiraz
		Province	Fars
		Postal code	۷۱۳۴۸۴۵۷۹۴
Public title		Approval date	2022-07-16, 1401/04/25
Evaluating the effectiveness of the stress ball for the management of botulinum toxin injection pain: a randomized controlled trial		Ethics committee reference number	IR.SUMS.MED.REC.1401.201
Purpose		Health conditions studied	
Supportive		1	
Inclusion/Exclusion criteria		Description of health condition studied	
Inclusion criteria:		Skin Wrinkle	
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.		ICD-10 code	
Exclusion criteria:		L98.9	
No history of allergy to Botox		ICD-10 code description	
Age		Disorder of the skin and subcutaneous tissue, unspecified	
From 18 years old		Primary outcomes	
Gender		1	
Both		Description	
Phase		Injection pain	
2		Timepoint	
Groups that have been masked		Immediately after injection	
No information		Method of measurement	
Sample size		Visual Analog Scale (VAS) questionnaire	
Target sample size: 40		Secondary outcomes	
Randomization (investigator's opinion)		empty	
Randomized		Intervention groups	
Randomization description		1	
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.		Description	
Blinding (investigator's opinion)		Intervention group: participants were asked to squeeze stress balls in both hands during the BT injection (on one side of the face).	
Not blinded		Category	
Blinding description		Treatment - Devices	
Placebo		2	
Not used		Description	
Assignment		Control group: the group that does nothing during BT injection (on one side of the face).	
Parallel		Category	
Other design features		Treatment - Devices	
Secondary Ids		Recruitment centers	
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			

1

Recruitment center

Name of recruitment center

Shahid Faghihi Hospital

Full name of responsible person

Mohammad Reza Namazi

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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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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