

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Management of synkinesis with a combination of BTX-A and biofeedback: A randomized trial

Protocol summary

Summary

Abstract Objective: The aim of this study was to investigate the efficacy of combination of biofeedback and BTX-A injection for management of synkinesis. Among referral patients from three university hospitals. Inclusion criteria is Bell' palsy with synkinesis and exclusion criteria is hami facial spasm. Thirty four patients with facial synkinesis are divided randomly into 2 groups. All the participants were evaluated by videotape and facial grading system. The first group as a Botox group, received single dose of BTX-A (Dysport) in the initiation of treatment. The second group received Normal Saline as control group. Both groups received EMG biofeedback 3 sessions in a week for 4 months

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201309256083N3**

Registration date: **2013-10-07, 1392/07/15**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2013-10-07, 1392/07/15

Registrant information

Name

Abbas Ali Pourmomeny

Name of organization / entity

School of Rehabilitation Sciences, Isfahan University of Medical Sciences, Isfahan, Iran

Country

Iran (Islamic Republic of)

Phone

+98 31 1792 2024

Email address

pourmomeny@rehab.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Research Center of Isfahan University of Medical Sciences

Expected recruitment start date

2012-04-21, 1391/02/02

Expected recruitment end date

2013-07-23, 1392/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Management of synkinesis with a combination of BTX-A and biofeedback: A randomized trial

Public title

Management of synkinesis with a combination of BTX-A and biofeedback

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Bell' palsy with synkinesis Exclusion criteria: hami facial spas

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **34**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

symetric face muscles

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Committee Medical Ethics of the "Isfahan University of medical Sciences"

Street address

Committee for Medical Ethics of the "Isfahan University of medical Sciences"

City

Isfahan

Postal code

Approval date

2012-09-23, 1391/07/02

Ethics committee reference number

392390

Health conditions studied

1

Description of health condition studied

Bell's palsy

ICD-10 code

G51.0

ICD-10 code description

Facial palsy

Primary outcomes

1

Description

synkinesis

Timepoint

before and after treatment videotape

Method of measurement

videotape & facial grading system

Secondary outcomes

empty

Intervention groups

1

Description

Botox-A

Category

Treatment - Drugs

2

Description

biofeedback therapy

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Rehabilitation Sciences of " Isfahan University of Medical Sciences"

Full name of responsible person

Pourmomeny

Street address

Rehabilitation Sciences of "Isfahan University of Medical Sciences"

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Center of research of Medical Sciences of "Isfahan University"

Full name of responsible person

Adibi

Street address

Center of research of Medical Ethics of the "Isfahan University of Medical Sciences"

City

Isfahan

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Center of research of Medical Sciences of "Isfahan University"

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Department of physical therapy, School of Rehabilitation Sciences, "Isfahan University of Medical Sc

Full name of responsible person

pourmomeny

Position

Instctor

Other areas of specialty/work

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Web page address

Person responsible for updating data

Contact

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty