Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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

Street address

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

City

Isfahan

Postal code

Phone

+98 31 1792 2024

Fax

Email

pourmomeny@rehab.mui.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

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

Full name of responsible person

pourmomeny

Position

Msc

Other areas of specialty/work

Street address

Department of physical therapy, School of Rehabilitation Sciences, "Ishahan University of Medical Sciences"

City

Isfahan

Postal code

Phone

+98 31 1792 2024

Fax

Email

pourmomeny@rehab.mui.ac.ir

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