

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Comparing efficacy neuromuscular Retraining and Botox in sequel of facial nerve palsy

Protocol summary

Summary

Synkinesis is one of the most unpleasant sequel of peripheral facial nerve palsy. It refers to the abnormal involuntary facial movement accompanying the voluntary movement of a different facial muscle group. The aim of this study was to investigate the efficacy of biofeedback and Botulinum A Toxin injection to improve synkinesis and symmetry in facial nerve palsy. The sequel of facial nerve palsy will be included. Upper motor neuron lesion, hemifacial spasm and bilateral facial nerve palsy will be excluded. 30 subjects with facial nerve palsy were randomly divided into two groups. The first group will receive Botulinum toxin A injection around the mouth and eye (synkinesis area). The control group, will take part in four-months rehabilitation program including Neuromuscular reeducation by biofeedback immediately after saline injection as a placebo. All subjects will be evaluated by facial grading system and video type. The final evaluation will be conducted four months after treatment. The Both groups will be compared using facial grading system.(Sunny Brook system).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201612136083N10**
Registration date: **2017-03-14, 1395/12/24**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-03-14, 1395/12/24

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)

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Recruitment status

Recruitment complete

Funding source

Vice-Chancellor's Office for Research in Isfahan University of Medical Sciences

Expected recruitment start date

2016-03-19, 1394/12/29

Expected recruitment end date

2017-03-20, 1395/12/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing efficacy neuromuscular Retraining and Botox in sequel of facial nerve palsy

Public title

Treatment sequel of facial nerve palsy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion: incomplete recovery facial nerve palsy ; Asymmetry in facial muscles during Expression Exclusion : upper motor neuron lesion ; Bilateral facial nerve palsy ; hamifacial spasm palsy

Age

No age limit

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethical committee of Isfahan University of Medical Sciences

Street address
Isfahan University of Medical Sciences

City
Isfahan

Postal code

Approval date
2016-04-26, 1395/02/07

Ethics committee reference number
IR.MUI.REC.1395.3.128

Health conditions studied

1

Description of health condition studied
Facial palsy

ICD-10 code
G51.0

ICD-10 code description
Bell palsy

Primary outcomes

1

Description
Synkinesis

Timepoint

Before treatment

Method of measurement
Vedio type & sunny Brook Scale(facial grading scale)

2

Description
Asymmetry face

Timepoint
Before treatment

Method of measurement
Vedio type & sunny Brook Scale(facial grading scale)

Secondary outcomes

1

Description
Synkinesis

Timepoint
After treatment

Method of measurement
Vedio type & facial grading scale

2

Description
Asymmetry

Timepoint
After treatment

Method of measurement
Vedio type & facial grading scale

Intervention groups

1

Description
biofeedback group:Neuromuscular retraining for 4 months

Category
Treatment - Drugs

2

Description
botox A group: 15- 20 unite toxin type A (Dysport) injections in the face (around the synkinesis muscles)

Category
Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center
Alzahra Hospital

Full name of responsible person
Pourmomeny

Street address
Isfahan University of Medical Sciences

City
Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-Chancellor's Office In Isfahan University of
Medical Sciences

Full name of responsible person

Dr.Nematbaghsh

Street address

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

Vice-Chancellor's Office In Isfahan University of Medical
Sciences

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

Isfahan University of Medical Sciences

Full name of responsible person

Abbas Ali Pourmomeny

Position

Academic member

Other areas of specialty/work

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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