Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

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

Protocol summary

Summary

Synkinesis is one of the most unpleasant squeal 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

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Name of organization / entity

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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

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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

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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