

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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)

##### Phone

+98 31 1792 2024

##### Email address

pourmomeny@rehab.mui.ac.ir

##### 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**  
Acadmic member

**Other areas of specialty/work**

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## Person responsible for scientific

## inquiries

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Instuctor

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## Person responsible for updating data

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Planer/designer

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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*