

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

01 Aug 2026

### Clinical effect of Bupivacain injection in orbicularis oculi muscle in patient with facial nerve palsy.

#### Protocol summary

##### Summary

This study is a clinical trial on clinical effect of Bupivacain injection in orbicularis oculi muscle in patients with facial nerve palsy. The control group of these patients were themselves and the method of this study was before after. The subjects were cases recruited using the inclusion and exclusion criteria at Farabi eye hospital (Tehran, Iran) clinic from January 2012 to June 2013. Inclusion criterion: patients with partial facial nerve palsy and ocular involvement who referred to us at least 12 weeks after the onset of symptoms. Exclusion criteria: complete facial nerve palsy; traumatic palsy; corneal ulcer; immediate need to surgical intervention; 3rd and 4th cranial nerve palsy and any type of strabismus. Fifteen patients were selected; after examination and measurement of indexes, bupivacain 0.75(4cc) was injected in pretarsal and preseptal part of orbicularis oculi muscle of upper and lower lids. This injection was done again after 3 weeks and then after 1, 3, 6 months the patients were visited and indexes were measured. The study outcome was clinical response to treatment and the amount of orbicularis oculi muscle hypertrophy in improvement of indexes. Primary outcome of this study was the amount of changes in vertical palpebral fissure height in open and close eye after injection.

#### General information

##### Acronym

BT7

##### IRCT registration information

IRCT registration number: **IRCT2013022712637N1**

Registration date: **2013-04-18, 1392/01/29**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2013-04-18, 1392/01/29

##### Registrant information

###### Name

Mahla Shadravan

###### Name of organization / entity

Tehran University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 5536 9786

###### Email address

mshadravan.opht@gmail.com

##### Recruitment status

###### Recruitment complete

##### Funding source

Ophthalmology Research Center, Tehran University of Medical Sciences

##### Expected recruitment start date

2011-12-22, 1390/10/01

##### Expected recruitment end date

2013-04-21, 1392/02/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Clinical effect of Bupivacain injection in orbicularis oculi muscle in patient with facial nerve palsy.

##### Public title

Bupivacain injection effect in orbicularis muscle in partial facial nerve palsy

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criterion: patients with partial facial nerve palsy

and ocular involvement who referred to us at least 12 weeks after the onset of symptoms. Exclusion criteria: complete facial nerve palsy; traumatic palsy; corneal ulcer; immediate need to surgical intervention; third and forth cranial nerve palsy and any type of strabismus.

**Age**

No age limit

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

No information

**Sample size**

Target sample size: 15

**Randomization (investigator's opinion)**

N/A

**Randomization description****Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Single

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ophthalmology Research Center Ethics Committee,  
Tehran University of Medical Sciences of Tehran Univ

**Street address**

Qazvin squer, farabi eye hospital

**City**

Tehran

**Postal code****Approval date**

2011-09-23, 1390/07/01

**Ethics committee reference number**

ERC/S/153

**Health conditions studied****1****Description of health condition studied**

Partial peripheral facial nerve palsy

**ICD-10 code**

G64

**ICD-10 code description**

Disorder of peripheral nervous system NOS

**Primary outcomes****1****Description**

Orbicularis muscle function

**Timepoint**

One month, 3 months and 6 months after first exam

**Method of measurement**

Questionnaire

**Secondary outcomes****1****Description**

Palpebral fissure hight in open and close eye

**Timepoint**

1, 3 and 6 months after first exam

**Method of measurement**

milimeter

**2****Description**

Marginal reflex distance 1 and 2

**Timepoint**

1, 3 and 6 months after first exam

**Method of measurement**

milimeter

**3****Description**

Scleral show in close eye

**Timepoint**

1, 3 and 6 months after first exam

**Method of measurement**

milimeter

**4****Description**

Corneal exposure in closed eye

**Timepoint**

1, 3 and 6 months after first exam

**Method of measurement**

milimeter

**5****Description**

Epiphora and its severity

**Timepoint**

1, 3 and 6 months after first exam

**Method of measurement**

Subjective

**Intervention groups**

1

**Description**

Four cc bupivacaine 0.75 was injected in pre tarsal and pre septal part of orbicularis muscle. Two and 4 weeks later this injection was done again.

**Category**

Treatment - Drugs

**Recruitment centers**

1

**Recruitment center**

**Name of recruitment center**

Farabi Eye hospital

**Full name of responsible person**

Mahla Shadravan

**Street address**

Qazvin squer

**City**

Tehran

**Sponsors / Funding sources**

1

**Sponsor**

**Name of organization / entity**

Ophthalmology research center of Tehran university of medical science

**Full name of responsible person**

Dr Ali Sadeghi Tari

**Street address**

Qazvin squar, Farabi Eye hospital

**City**

Tehran

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Ophthalmology research center of Tehran university of medical science

**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**

Tehran University of Medica, Farabi eye hospital

**Full name of responsible person**

Mahla Shadravan

**Position**

MD, Resident of ophthalmology

**Other areas of specialty/work**

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**Person responsible for scientific inquiries**

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**Name of organization / entity**

Tehran University of Medical Sceinces, Farabi eye hospital

**Full name of responsible person**

Mohammad Taher Rajabi

**Position**

ophthalmologist. Oculoplastic surgery fellowship

**Other areas of specialty/work**

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**Email**

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**Web page address**

**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*