

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 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

Contact

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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Person responsible for updating data

Contact

Name of organization / entity

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Position

MD, Resident of ophthalmology

Other areas of specialty/work

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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