

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 Jun 2026

### Comparison of the effects of combination therapy of Prednisolone and Acyclovir with Prednisolone alone in Bell's palsy patients aged 2-18 years

#### Protocol summary

##### Summary

Bell's palsy is a condition characterized by an acute onset of facial nerve palsy. Treatment of Bell palsy varies, and no clear consensus exists. Most physicians prescribe corticosteroids as a primary treatment. However, due to possible conflicts with the treatment of HSV and other viral infections virus also seems logical. There is insufficient evidence to support the use of anti-virus and it is contraversion. Based on the serological evidence obtained, some experts treated patients with Anti-virus, including acyclovir, valacyclovir Famcyclovir. Our goal is to enable patients to benefit from this treatment. This study is a clinical trial. The severity of the disease and improve the treatment of Bell's palsy is measured according to Table House Bruckman. A sample of 100 patients admitted to the pediatric clinic based and randomly divided into two groups. A: Combination therapy with prednisone and acyclovir B: Treatment with prednisolone alone Inclusion Criteria: 1. aged 2 to 18 years 2. Patients who have just seventh nerve palsy. 3. No more than three days after the symptoms have passed. After investigating the specific cause is not found for seven nerve palsy. Exclusion Criteria: 1. Patients with paralysis of the seventh nerve palsy, other cranial nerves are. 2. Be over the last three days of onset of symptoms. 3. After examining the specific cause is found for paralysis. 4. The last two weeks of treatment is anti-herpetic received. 5. Be sensitive to acyclovir

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2012062210087N1**

Registration date: **2013-11-10, 1392/08/19**

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

Last update:

Update count: **0**

##### Registration date

2013-11-10, 1392/08/19

##### Registrant information

###### Name

Ali Khajeh

###### Name of organization / entity

Zahedan University Of Medical Science

###### Country

Iran (Islamic Republic of)

###### Phone

+54 13220316

###### Email address

khajeha@zaums.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Zahedan University of Medical Sciences Deputy of Research and Technology

##### Expected recruitment start date

2011-09-20, 1390/06/29

##### Expected recruitment end date

2014-03-21, 1393/01/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of the effects of combination therapy of Prednisolone and Acyclovir with Prednisolone alone in Bell's palsy patients aged 2-18 years

##### Public title

Efficacy of corticosteroid and acyclovir in Bell's palsy

##### Purpose

Treatment

## Inclusion/Exclusion criteria

Inclusion Criteria: 1. aged 2 to 18 years 2. Patients who have just seventh nerve palsy. 3. No more than three days after the symptoms have passed. After investigating the specific cause is not found for seven nerve palsy. Exclusion Criteria: 1. Patients with paralysis of the seventh nerve palsy, other cranial nerves are. 2. Be over the last three days of onset of symptoms. 3. After examining the specific cause is found for paralysis. 4. The last two weeks of treatment is anti-herpetic received. 5. Be sensitive to acyclovir

## Age

From **2 years** old to **18 years** old

## Gender

Both

## Phase

N/A

## Groups that have been masked

*No information*

## Sample size

Target sample size: **100**

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Not blinded

## Blinding description

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Zahedan University of Medical Sciences

##### Street address

Daneshgah street, Dr Hesabi square, zahedan university of medical sciences, campus

##### City

Zahedan

##### Postal code

#### Approval date

2011-12-02, 1390/09/11

#### Ethics committee reference number

90-2049

## Health conditions studied

### 1

#### Description of health condition studied

bell palsy

#### ICD-10 code

G51.0

#### ICD-10 code description

Bell palsy

## Primary outcomes

### 1

#### Description

severity of palsy according to house\_brackmann scale

#### Timepoint

1 and 2 month after treatment

#### Method of measurement

house\_brackmann scale

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

The first group Prednisolone 2 mg per kg of body weight to be given seven days

#### Category

Treatment - Drugs

### 2

#### Description

The second group of Prednisolone at a dose of 2 mg per kg of body weight, Acyclovir tablets of 20 mg per kg of body weight should be given for seven days.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Ali Asghar Hospital

##### Full name of responsible person

Ali khajeh

##### Street address

Ali Asghar Hospital, Zahedan

##### City

Zahedan

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Vice chancellor for research, Zahedan University of Medical Sciences

**Full name of responsible person**

Hamidreza mahmoodzade sagheb

**Street address**

Zahedan University of Medical Sciences

**City**

Zahedan

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Vice chancellor for research, Zahedan 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**

Zahedan University of Medical Science

**Full name of responsible person**

Sara Sheikhveisi

**Position**

stager

**Other areas of specialty/work****Street address**

Emam Ali Hospital

**City**

Zahedan

**Postal code****Phone**

+98 54 1242 1638

**Fax****Email**

s\_sheikhveisi@yahoo.com

**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Zahedan University of Medical Science , Zahedan , Iran

**Full name of responsible person**

Ali Khajeh

**Position**

Pediatric neurologist

**Other areas of specialty/work****Street address**

Ali Asghar Hospital

**City**

Zahedan

**Postal code****Phone**

+98 54 1322 0316

**Fax****Email**

drkhajehneuro@gmail

**Web page address****Person responsible for updating data****Contact****Name of organization / entity**

Zahedan University of Medical Science

**Full name of responsible person**

Sara Sheikhveisi

**Position**

stager

**Other areas of specialty/work****Street address**

Emam Ali Hospital

**City**

Zahedan

**Postal code****Phone**

+98 54 1242 1638

**Fax****Email**

s\_sheikhveisi@yahoo.com

**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*