

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparison of therapeutic effects of prednisolone, acyclovir, and combination of these drugs in Bell's Palsy

#### Protocol summary

##### Summary

Idiopathic facial nerve paralysis is the most common cause of acquired, acute and non-traumatic facial nerve paralysis which is usually unilateral. Objectives: This study investigated the effect of single acyclovir or prednisolone and their combination therapy in the treatment of facial nerve palsy. Design: To do this, a randomized, study was designed without the use of placebos. Participants including major eligibility criteria: Therefore all patients over ten years of age with unilateral facial nerve palsy were entered into the study and all patients who were found to have a cause for their palsy or more than 7 days had passed from the onset of their palsy were excluded from the study. The sample size was equal to 180. All Setting and conduct: patients were graded according to House-Brackman criteria and then randomly divided into three groups. Intervention: The first group received 1 mg/kg prednisolone for 15 days and then the drug was gradually tapered, the second group received 400 mg oral acyclovir every 5 hours per day for 10 days, and the third group received a combination of these two drugs. Then the patients were followed up every 15 days for 3 months and the facial nerve function was assessed using House-Brackmann score. Main outcome measures: Changes in House-Brackman grades is our primary outcome measure.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201109187575N1**  
Registration date: **2011-11-20, 1390/08/29**  
Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2011-11-20, 1390/08/29

##### Registrant information

###### Name

Alireza Rezaei Ashtiani

###### Name of organization / entity

Arak University Of Medical Science

###### Country

Iran (Islamic Republic of)

###### Phone

+98 86 1222 7828

###### Email address

dr.ashtiani@arakmu.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Arak University of Medical Sciences, Vice chancellor for research

##### Expected recruitment start date

2010-05-22, 1389/03/01

##### Expected recruitment end date

2011-08-22, 1390/05/31

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of therapeutic effects of prednisolone, acyclovir, and combination of these drugs in Bell's Palsy

##### Public title

Comparison of therapeutic effects of prednisolone, acyclovir, and combination of these drugs in Bell's Palsy

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion Criteria: Patients with Bell's palsy; Age over 10 years  
Exclusion Criteria: More than 7 days have passed since the onset of paralysis; Finding another cause for the paralysis

#### Age

From **10 years** old to **149 years** old

#### Gender

Both

#### Phase

2

#### Groups that have been masked

No information

#### Sample size

Target sample size: **180**

#### 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

Ethical committee of Arak University Of Medical Science

##### Street address

Alamalhoda ave, Parastar Square, Arak University of Medical Sciences

##### City

Arak

##### Postal code

#### Approval date

2010-04-27, 1389/02/07

#### Ethics committee reference number

89-77-3

## Health conditions studied

### 1

#### Description of health condition studied

Bell's palsy

#### ICD-10 code

G51.0

#### ICD-10 code description

Facial palsy

## Primary outcomes

### 1

#### Description

House-Brackmann score

#### Timepoint

Each 15 days

#### Method of measurement

Calculate House-Brackmann score

## Secondary outcomes

### 1

#### Description

Failure to treatment

#### Timepoint

The end of month 3

#### Method of measurement

No reduce of House-Brackmann score

## Intervention groups

### 1

#### Description

prednisone, a dose of 1 mg/kg body weight was given daily for 3 days. The treatment was tapered over the next 12 days

#### Category

Treatment - Drugs

### 2

#### Description

Acyclovir, 400 mg every 5 hours per day for 10 days

#### Category

Treatment - Drugs

### 3

#### Description

Prednisone, a dose of 1 mg/kg body weight was given daily for 3 days. The treatment was tapered over the next 12 days. Those taking acyclovir received 400 mg every 5 hours per day for 10 days

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Valie-Asr Hospital

##### Full name of responsible person

Dr Alireza Rezaei Ashtiani

##### Street address

Valie-Asr Hospital , Pirozi Ave, Arak

##### City

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Arak University of Medical Sciences,Vice chancellor for research

**Full name of responsible person**

Dr Saied Changizi Ashtiani

**Street address**

Arak University of Medical Sciences , Basij square,Arak

**City**

Arak

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

Yes

**Title of funding source**

Arak University of Medical Sciences,Vice chancellor for research

**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**

Arak University of Medical Sciences

**Full name of responsible person**

Dr Alireza Rezaei Ashtiani

**Position**

Neurologist,Assistant professor

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**Street address**

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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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*