

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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

Other areas of specialty/work

Street address

Department of Internal Medicine,Valie-Asr
Hospital,Pirozi Ave.Arak

City

Arak

Postal code

3814957558

Phone

+98 86 1224 1411

Fax

+98 86 1224 1411

Email

dr.ashtiani@arakmu.ac.ir

Web page address

portal.arakmu.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Dr Alireza Rezaei Ashtiani

Position

Neurologist,Assistant professor

Other areas of specialty/work

Street address

Department of Internal Medicine,Valie-Asr
Hospital,Pirozi Ave.Arak

City

Arak

Postal code

3814957558

Phone

+98 86 1224 1411

Fax

+98 86 1224 1411

Email

dr.ashtiani@arakmu.ac.ir

Web page address

portal.arakmu.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Dr Alireza Rezaei Ashtiani

Position

Neurologist,Assistant professor

Other areas of specialty/work

Street address

Department of Internal Medicine,Valie-Asr
Hospital,Pirozi Ave.Arak

City

Arak

Postal code

3814957558

Phone

+98 86 1224 1411

Fax

+98 86 1224 1411

Email

dr.ashtiani@arakmu.ac.ir

Web page address

portal.arakmu.ac.ir

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