Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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

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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

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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
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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

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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