

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jun 2026

Comparison of efficacy and side-effects of Phenytoin versus Oxcarbazepine in secondary generalized epilepsy in the elderly

Protocol summary

Summary

Objective: In this study has been compared the efficacy and tolerability of Phenytoin versus Oxcarbazepine in the newly diagnosed elderly patients with secondary generalized epilepsy. Methods: We enrolled in this study 142 elderly patients with epilepsy that referred to Neurology clinic of Ahvaz Golestan Hospital after considering the measures of exclusion and inclusion criteria. (Inclusion criteria: Age greater than 65 years old; Not having acute treatable cause; Having secondary generalized epilepsy according to history And Exclusion criteria: Previous history of reaction to phenytoin or Oxcarbazepine; Having other causes except cerebrovascular disease as primary cause of epilepsy). Then the patients were divided in two groups randomly. For one group were administered phenytoin capsule (greater than 70 years old, 100mg, twice daily & lesser than 70 years old, 100mg, three times daily) And the other group, oxcarbazepine tablet 300mg, twice daily in a double blind manner for 6 months. In this period patients were followed up for side effects and their response to treatment (not having seizure).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201202068943N1**

Registration date: **2012-03-17, 1390/12/27**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2012-03-17, 1390/12/27

Registrant information

Name

Mehran Keshavarzi

Name of organization / entity

Golestan Hospital

Country

Iran (Islamic Republic of)

Phone

+98 61 1320 9577

Email address

keshavarzi.m@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice-Chancellor in research of Ahvaz Jundishapur University

Expected recruitment start date

2010-11-26, 1389/09/05

Expected recruitment end date

2011-06-10, 1390/03/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of efficacy and side-effects of Phenytoin versus Oxcarbazepine in secondary generalized epilepsy in the elderly

Public title

efficacy of Oxcarbazepine and Phenytoin in control of epilepsy in the elderly

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Age greater than 65 y/o; Not having acute treatable cause; Having secondary generalized epilepsy according to history and Exclusion criteria: Previous history of reaction to phenytoin or

Oxcarbazepine; Having other causes except cerebrovascular disease as primary cause of epilepsy.

Age

From **65 years** old to **87 years** old

Gender

Both

Phase

4

Groups that have been masked

No information

Sample size

Target sample size: **142**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ahvaz Jundishapur University

Street address

Medical Science Faculty

City

Ahvaz

Postal code

61335

Approval date

2010-06-12, 1389/03/22

Ethics committee reference number

245/د

Health conditions studied

1

Description of health condition studied

epilepsy

ICD-10 code

G40.1

ICD-10 code description

Localization-related (focal)(partial) symptomatic epilepsy and epileptic syndromes with simple partial seizures

2

Description of health condition studied

epilepsy

ICD-10 code

G40.2

ICD-10 code description

Localization-related (focal)(partial) symptomatic epilepsy and epileptic syndromes with complex partial seizures

Primary outcomes

1

Description

Dizziness

Timepoint

at onset,after 2 weeks,1 month, 2 months,4 months and 6 months

Method of measurement

History and physical examination

2

Description

Nausea and vomiting

Timepoint

at onset,after 2 weeks,1 month, 2 months,4 months and 6 months

Method of measurement

History and physical examination

3

Description

Ataxia

Timepoint

at onset,after 2 weeks,1 month, 2 months,4 months and 6 months

Method of measurement

History and physical examination

4

Description

Somnolence

Timepoint

at onset,after 2 weeks,1 month, 2 months,4 months and 6 months

Method of measurement

History and physical examination

5

Description

Lethargy

Timepoint

at onset,after 2 weeks,1 month, 2 months,4 months and 6 months.

Method of measurement

History and physical examination

6

Description

Skin reaction

Timepoint

at onset,after 2 weeks,1 month, 2 months,4 months and 6 months.

Method of measurement

History and physical examination

7**Description**

gingival hyperplasia

Timepoint

at onset,after 2 weeks,1 month, 2 months,4 months and 6 months.

Method of measurement

History and physical examination

8**Description**

Seizure symptoms

Timepoint

at onset,after 2 weeks,1 month, 2 months,4 months and 6 months.

Method of measurement

History and physical examination

Secondary outcomes

empty

Intervention groups**1****Description**

For the group A were administered phenytoin capsule 100mg (>70 y/o 100mg BID & <70 y/o 100mg TDS) and placebo tablet 150mg started 150mg,BID and increased to 300mg BID during 2 weeks.the course of treatment was 6months.

Category

Treatment - Drugs

2**Description**

the group B oxcarbazepine 150mg (300mg, BID) was administered.that started with 150 mg BID and increased to 300mg BID during 2weeks. also placebo capsule 100mg(>70 y/o,BID &<70y/o, TDS) was administered.the course of treatment was 6months.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Special Clinic of Neurology of Golestan Hospital

Full name of responsible person

Mehran Keshavarzi MD, Resident of Neurology

Street address

Department of Neurology(Golestan Hospital)

City

Ahvaz

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Vice-chancellor in Reaserch of Jondishapur University

Full name of responsible person

Khosravi Azardokht MD

Street address

Medical Science Facaulty

City

Ahvaz

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

Yes

Title of funding source

Vice-chancellor in Reaserch of Jondishapur University

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**

Medical Science Facaulty

Full name of responsible person

Mehran Keshavarzi

Position

Neurology Resident

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

Ahvaz Jundishapur University

City

Ahvaz

Postal code**Phone**

+98 61 1373 8302

Fax**Email**

Keshavarzi.m@ajums.ac.ir

Web page address**Person responsible for scientific**

inquiries

Contact

Name of organization / entity

Medical Science Faculty

Full name of responsible person

Mehran Keshavarzi

Position

Neurology Resident

Other areas of specialty/work

Street address

Jondishapur University

City

Ahvaz

Postal code

61335

Phone

+98 61 1373 8302

Fax

+98 61 1333 2036

Email

Keshavarzi.m@ajums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Medical Science Faculty

Full name of responsible person

Mehran Keshavarzi

Position

Neurology Resident

Other areas of specialty/work

Street address

Jundishapur University

City

Ahvaz

Postal code

61335

Phone

+98 61 1373 8302

Fax

+98 33 32036

Email

keshavarzi.m@ajums.ac.ir

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