Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparison efficacy of depakin and phenytoin in aborting serial seizures.

Protocol summary

Summary

The purpose of this study is comparing therapeutic effects of two common anti epileptic drugs; phenytoin and depakin; in aborting serial seizures. Our inclusion criteria are age older than 18 years old and at least two tonic- clonic generalized seizures (with complete recovery of consciousness between them) during last 24 hours. Exclusion criteria including status epilepticus, pregnancy and presence of any contraindication for administration phenytoin or depakin such as heart block, hepatic failure and .... Sample size will be sixty patients that will be divided in two groups according to random chart. One group receiving intravenous phenytoin 18mg/kg and other group receiving intravenous depakin 20mg/kg stat that will continue with maintenance dose at 1mg/kg/hour for 24 hours. All patients will be under close observation for 24 hours after administration of drugs. Drug efficacy defined as complete cease of seizures that will be evaluate during 24 hours after administration of drugs.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013012012208N1**
Registration date: **2013-04-28, 1392/02/08**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2013-04-28, 1392/02/08

Registrant information

Name

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Vice-Chancellery of Research and Technology, Shiraz University of Medical Sciences

Expected recruitment start date

2013-02-03, 1391/11/15

Expected recruitment end date

2013-03-05, 1391/12/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison efficacy of depakin and phenytoin in aborting serial seizures.

Public title

comparison of depakin and phenytoin in serial seizures

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1-age>18y/o 2- SS is defined as 2 generalized tonic clonic seizures in 1 hour or more than 2 generalized tonic clonic seizures in 24 hours. Patients should regain full level of consciousness between attacks. Exclusion criteria: 1-Status epilepticus 2-Pregnancy 3-Hepatic failure 4-renal failure 5-Younger than 18 years old phenytoin such as heart disease, drug sensivity, systolic blood pressure less than 100mmhg, heart rate less than 60/min

Age

From **18 years** old to **100 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Shiraz University Of Medical Sciences

Street address
Shiraz University Of Medical Sciences, Zand Boulevard, Shiraz

City
Shiraz

Postal code
7134814336

Approval date
2012-07-12, 1391/04/22

Ethics committee reference number
ct-91-1950

Health conditions studied

1

Description of health condition studied
Epilepsy

ICD-10 code
G40.3

ICD-10 code description
Generalized idiopathic epilepsy and epileptic syndromes

Primary outcomes

1

Description
number of seizures during 24 hours after treatment

Timepoint
24 hours

Method of measurement
observe patient and completing a form

Secondary outcomes

1

Description
cardiac rhythm

Timepoint
continuous monitoring

Method of measurement
Heart minitoring device

2

Description
Blood pressure

Timepoint
continuous monitornig

Method of measurement
Digital blood pressure manitor

3

Description
Haert Rate

Timepoint
Continuous Monitoring

Method of measurement
Haert monitoring device

Intervention groups

1

Description
Administration Depakin (Na valproate) IV at dose 20mg/kg stat then 1mg/kg/hour for 24 hours

Category
Treatment - Drugs

2

Description
Administration Phenytoin (IV) at dose 18 mg/kg

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Shiraz Namazi Hospital

Full name of responsible person
Raeyat Mohammed Reza

Street address
Namazi Hospital, Namazi Square, Shiraz

City
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University Of Medical Sciences
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Vice-Chancellery of Research and Technology
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Shiraz University Of Medical Sciences, Zand Boulevard, Shiraz
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Shiraz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shiraz 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

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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