

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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

Department of Neurology, Shiraz University Of Medical Sciences

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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 monitoring device

2

Description

Blood pressure

Timepoint

continuous monitoring

Method of measurement

Digital blood pressure monitor

3

Description

Heart Rate

Timepoint

Continuous Monitoring

Method of measurement

Heart 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
Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University Of Medical Sciences

Full name of responsible person

Vice-Chancellery of Research and Technology

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Shiraz University Of Medical Sciences, Zand
Boulevard, Shiraz

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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

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

Contact

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Department of Neurology, Shiraz University Of
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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