

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jul 2026

Comparison of Effectiveness of Levetiracetam With Phenytoin in Postcraniotomy Seizure in the Patients with Supratentorial Brain Tumors:RCT-Single Blind

Protocol summary

Study aim

Comparison of the Effectiveness of the Phenytoin with the Levetiracetam on Pre&Postcraniotomy Seizure in the Supratentorial Brain Tumors Patients.

Design

The study is randomized clinical trials that include the patients with definitive diagnosis of supratentorial brain tumors&need to craniotomy.After entrance, the patients arrangements by randomization with proportion 1:1 in two groups of Phenytoin&Levetiracetam.The block randomization is used in the study.Seizure after onset of drugs or drug complications are on the ground of treatment failure.The two groups compare together.In the study exist extent of tumor resection,postop edema&hematoma,maximum of the brain mass diameter,pathology&duration of the surgery.before onset of the study,the purposes&type of the study&form of performance explain to the patients&get written consent from the patients for play at the study.the numbers of every group is 40&clinical trial phase is 3.

Settings and conduct

the location of the study is shariati hospital&the study is single blind.the examiner is blind.

Participants/Inclusion and exclusion criteria

The patients with age higher from 18years with Supratentorial Tumors need to Craniotomy&Liver & Renal function,Creatinine lower from 1.5× upper limit of normal (ULN), Aspartate Aminotransferase lower from 3× ULN, Alanine Aminotransferase lower from 3× ULN and Bilirubin lower from 1.5× ULN).Exclusion criterias are history of seizure before onset the drugs,skin complications,concurent of skull tumor&brain events examples CVA(Cerebrovascular Accident)&injury of the truma&infratentorial tumors.Advantages & disadvantages of use of AED(Antiepileptic Drugs) explain to the patients that have not history of seizure before onset the prophylactic treatment.Also other exclusion

critrias are history of Allergy to the Two Drugs,History of Seizure,Posterior Fossa Tumors,Pregnancy&History of Colostomy.

Intervention groups

One group receives the Phenytoin&another receives the levetiracetam.The complications check in every group.

Main outcome variables

The Seizure,Skin,Renal & Liver complications.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150419021837N1**

Registration date: **2017-12-19, 1396/09/28**

Registration timing: **registered_while_recruiting**

Last update: **2017-12-19, 1396/09/28**

Update count: **0**

Registration date

2017-12-19, 1396/09/28

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8490 2272

Email address

m-faghih@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2016-09-22, 1395/07/01

Expected recruitment end date

2019-02-20, 1397/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Effectiveness of Levetiracetam With Phenytoin in Postcraniotomy Seizure in the Patients with Supratentorial Brain Tumors:RCT-Single Blind

Public title

Comparison of Effectiveness of Levetiracetam With Phenytoin in Postcraniotomy Seizure in the Patients with Supratentorial Brain Tumors :RCT-Single Blind

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

The patients with age higher from 18years with Supratentorial Tumors need to Craniotomy&Liver & Renal function,Creatinine lower from1.5× upper limit of normal (ULN), Aspartate Aminotransferase lower from3× ULN, Alanine Aminotransferase lower from 3× ULN and Bilirubin lower from1.5× ULN)

Exclusion criteria:

History of Allergy to the Two Drugs,History of Seizure,Posterior Fossa Tumors,Pregnancy&History of Colostomy

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Not randomized

Randomization description**Blinding (investigator's opinion)**

Single blinded

Blinding description

The examiner does not know use which Drugs(Levetiracetam or Phenytoin)

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Tehran University of Medical Sciences

Street address

North karegar Ave,Shariati Hospital

City

Tehran

Province

Tehran

Postal code

1411713135

Approval date

2016-08-09, 1395/05/19

Ethics committee reference number

9311255001

Health conditions studied**1****Description of health condition studied**

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ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

siezure

Timepoint

Days of 7,30&90 Post Craniotomy

Method of measurement

Observation by the nurse or physicion

Secondary outcomes**1****Description**

Complications of Skin ,Renal&Liver

Timepoint

Days of 7,30&90 Post Craniotomy

Method of measurement

Observation of Skin &Liver&Renal lab data

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

Intervention group: Prophylaxis of the drugs use begins from 5 days before the surgery to continues 90 days

after the surgery. Levetiracetam Dosage: 1gr Bid in the operation day then 500mg Bid IV OR Oral

Category

Prevention

2

Description

Intervention group: Prophylaxis of the drugs use begins from 5 days before the surgery to continues 90 days after the surgery. Phenytoin dosage: loading dose 10-15 mg /kg IV-maintenance 100mg tds IV OR Oral.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Shariati hospital

Full name of responsible person

Medi Abolfazli

Street address

North Karegar AVE-Shariati hospital

City

Tehran

Province

Tehran

Postal code

1411713135

Phone

+98 21 8490 2272

Email

mfaghihj@sina.tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mohammad Ali Sahraian

Street address

North karegar Ave, Shariati Hospital

City

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Email

m-faghihj@sina.tums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tehran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mehdi Abolfazli

Position

resident

Latest degree

Medical doctor

Other areas of specialty/work

Neurosurgery

Street address

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Phone

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Email

mehdiabolfali1366@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Morteza Faghih Jouybari

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Neurosurgery

Street address

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Email

m-faghihj@sina.tums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mehdi Abolfazli

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Neurosurgery

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Email

mehdiabolfazli1366@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All of data of participants

When the data will become available and for how long

6month after publication of results

To whom data/document is available

Researchers of university&scientific institutes.

Under which criteria data/document could be used

In case of requesting the results

From where data/document is obtainable

TO me

What processes are involved for a request to access data/document

Sending the email to me

Comments