Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of the effect of phenobarbital and levetiracetam in the treatment of neonatal abstinence syndrome as adjunctive therapy

Protocol summary

Study aim
Comparison of the effect of adjunctive therapy with phenobarbital and levetiracetam in the treatment of neonatal abstinence syndrome
Design
Comparison of the effect of phenobarbital and levetiracetam in the treatment of neonatal abstinence syndrome as adjunctive therapy
Settings and conduct
Neonatal Intensive care unit of Afzalipour Hospital of Kerman
Participants/Inclusion and exclusion criteria
Hospitalized neonates with a gestational age of 35 weeks and older with neonatal abstinence syndrome
Intervention groups
Infants hospitalized with neonatal abstinence syndrome
Main outcome variables
Duration of hospitalization Duration of treatment Readmission

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20211218053444N2**
Registration date: **2022-02-25, 1400/12/06**
Registration timing: **prospective**

Last update: **2022-02-25, 1400/12/06**
Update count: **0**
Registration date
2022-02-25, 1400/12/06

Registrant information
Name
Zahra Jamali
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2022-04-21, 1401/02/01
Expected recruitment end date
2022-09-21, 1401/06/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the effect of phenobarbital and levetiracetam in the treatment of neonatal abstinence syndrome as adjunctive therapy

Public title
Comparison of the effect of phenobarbital and levetiracetam in the treatment of neonatal abstinence syndrome
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Hospitalized neonates with a gestational age of 35 weeks and older with moderate to severe neonatal abstinence syndrome
Exclusion criteria:
Infants under 35 weeks of gestation Infants with intrauterine growth restriction Infants with congenital major anomalies Infants who have a cause other than

neonatal abstinence syndrome for their hospitalization

Age

From **1 day** old to **28 days** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

N/A

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

Afzalipour Educational and Medical Center - Kerman University of Medical Sciences

Street address

22 Bahman Blvd

City

kerman

Province

Kerman

Postal code

7616913355

Approval date

2021-10-16, 1400/07/24

Ethics committee reference number

IR.KMU.AH.REC.1400.165

Health conditions studied

1

Description of health condition studied

Neonatal abstinence syndrome

ICD-10 code

P96.1

ICD-10 code description

Neonatal withdrawal symptoms from maternal use of drugs of addiction

Primary outcomes

1

Description

Infants with neonatal abstinence syndrome

Timepoint

1,3,6,10,14

Method of measurement

Finnegan Scoring Criteria

2

Description

Response rate to adjuvant therapy with levotiracetam compared with phenobarbital

Timepoint

1,3,6,10,14

Method of measurement

Finnegan Scoring Criteria

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Neonates with neonatal abstinence syndrome underwent Adjunctive therapy with levetiracetam

Category

Treatment - Drugs

2

Description

Control group: Neonates with neonatal abstinence syndrome underwent Adjunctive therapy with phenobarbital

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Afzalipour Hospital

Full name of responsible person

زهراجمالی

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Sponsors / Funding sources

1

Sponsor
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Web page address
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Kerman 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

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available