

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 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

Country

Iran (Islamic Republic of)

Phone

+98 34 3132 8198

Email address

z.jamali@kmu.ac.ir

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

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

Name of organization / entity

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

زهرا جمالی

Street address

Emam Blvd., Afzalipour Hospital

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kerman

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7616913355

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+98 34 3132 8000
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z.jamali@kmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Kerman University of Medical Sciences
Full name of responsible person
Zahra Jamali
Street address
Emam Blvd., Afzalipour Hospital
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Postal code
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Phone
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Email
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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

Contact

Name of organization / entity
Kerman University of Medical Sciences
Full name of responsible person
Zahra Jamali
Position
Assistant Professor
Latest degree
Subspecialist
Other areas of specialty/work
Pediatrics
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Person responsible for scientific inquiries

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Person responsible for updating data

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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