Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of the effectiveness of Gabapentin with placebo in feeding improvement in feeding refusal infants age 3 to 6 months

Protocol summary

Study aim

Determining the effect of Gabapentin on the effective number of breast milk consumption and the volume of formula consumption in infants 3 to 6 months

Design

Clinical trial with control group, of parallel groups, randomized double-blind phase 3 on 64 patients

Settings and conduct

64 infants aged 3 to 6 months with refusal feeding disorder and normal examinations referred to pediatric gastrointestinal clinics in Isfahan who according to the standard reflux questionnaire, do not have reflux based on random permutation blocks in volume 4, classified on Gender is equally divided into case and control groups. Assignors to groups and mothers will be unaware of the allocation process and sequence. The case group is given gabapentin at a dose of 5 mg per kg body weight every 8 hours, and if it is not too drowsy at the end of the first week, the dose is increased to 10 mg per kg body weight. Before the start of the drug and at the end of the second week and the first month, the number of effective feeding times of breastfeeding and the volume of formula consumed by the infant (in cc) are recorded.

Participants/Inclusion and exclusion criteria

Including criteria: Age 3 to 6 months The score of the reflux questionary 16 or lower Absence of an acute or chronic disease Excluding criteria: The score of the reflux questionary greater than 16 Presence of an acute or chronic disease Starting of complementary foods

Intervention groups

Infants 3 to 6 months of age with refusal feeding disorder are given gabapentin in the case group and placebo in the control group.

Main outcome variables

infant feeding, use of anti-reflux drugs, change different formulas , cost of treatment

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190410043224N4**
Registration date: **2021-02-20, 1399/12/02**
Registration timing: **registered_while_recruiting**

Last update: **2021-02-20, 1399/12/02**
Update count: **0**

Registration date

2021-02-20, 1399/12/02

Registrant information

Name

Peiman Nasri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-02-19, 1399/12/01

Expected recruitment end date

2021-05-22, 1400/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effectiveness of Gabapentin with placebo in feeding improvement in feeding refusal infants age 3 to 6 months

Public title
"Effect of Gabapentin in treatment of feeding refusal disorder"
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age 3 to 6 months The score of reflux questionary 16 or lower Lack of an acute or chronic disease
Exclusion criteria:
The score of the reflux questionary greater than 16 Presence of an acute or chronic disease Starting of complementary foods
Age
From **3 months** old to **6 months** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **64**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients are divided into 2 equal case and control groups on sex by permutation blocks randomization in volume 4, using the R softwsre.
Blinding (investigator's opinion)
Double blinded
Blinding description
Individuals assigning infants to groups, as well as mothers will be unaware of the allocation process and sequence.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Isfahan University of Medical Sciences
Street address
Imam khomeini Ave
City
Isfahan
Province
Isfehan
Postal code
8195163381
Approval date
2021-02-04, 1399/11/16
Ethics committee reference number
IR.MUI.MED.REC.1399.970

Health conditions studied

1

Description of health condition studied
Infants feeding refusal disorder
ICD-10 code
R63.3
ICD-10 code description
Feeding difficulties

Primary outcomes

1

Description
Number of effective breastfeeding
Timepoint
At the beginning of the study and at the end of the second week and the first month
Method of measurement
The number of feedings from the mother's breast that lasts at least 10 minutes or the mother feels empty breasts and the volume of formula to cc

2

Description
volume of formula consumed
Timepoint
Before the intervention, the end of the second week and the end of the first month
Method of measurement
Frequency of breastfeeding that lasts at least 10 minutes or the mother feels empty breasts-volume of formula consumed in mililiter

Secondary outcomes

1

Description
restlessness
Timepoint
The end of the first months
Method of measurement
Asking from mother

Intervention groups

1

Description

Intervention group:Intervention group: The intervention group includes 32 infants aged 3 to 6 months who have feeding refusal and have no reflux or other acute or chronic disease. How to choose them is random and with the help of software and mothers and prescribing doctors do not know whether the drug or placebo is given to the infants.They are given gabapentin syrup, which contains 60 mg of the drug per cc, and is made by a pharmacologist, a faculty member of Isfahan University of Medical Sciences, who is a partner in the project, at a dose of 5 mg per kilogram of body weight every 8 hours. And if infant do not get too sleepy at the end of the first week the dose is rised to 10 mg per kilogram of body weight. The amount of milk consumed is recorded before the start of the drug and at the end of the second week and the first month.

Category

Treatment - Drugs

2

Description

Control group: Control group: In the control group, the same number of intervention groups of patients are randomly selected with the help of software and they are given a placebo with the same dose of the main drug. And monitoring them is like an intervention group. Mothers and prescribing physicians are not aware that the drug or placebo is given to the child. Medication is one of the basic ingredients of the main medicine and does not contain only gabapentin.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Hossein Hospital Gastroenterology Clinic

Full name of responsible person

Dr peiman nasri

Street address

Imam khomeini Ave

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peiman.nasri@med.mui.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Ahmad heydari

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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

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Ahmad Heydari

Position

pediatrician Gastroentrology fellow

Latest degree

Specialist

Other areas of specialty/work

Pediatrics

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Person responsible for scientific inquiries

Contact

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Full name of responsible person
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Position
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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