Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Jul 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
+98 31 3261 6331

Email address
peiman.nasri@med.mui.ac.ir

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
City
Isfahan
Province
Isfehan
Postal code
8195163381
Phone
+98 31 3386 6266
Email
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
Street address
Imam khomeini Ave
City
Isfahan
Province
Isfehan
Postal code
8195163381
Phone
+98 31 3386 6266
Email
heydari.pedres@gmail.com

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
Street address
Imam khomeini Ave
City
Isfahan
Province
Isfehan
Postal code
8195163381
Phone
+98 31 3386 6266
Email
heydari.pedres@gmail.com

Person responsible for scientific 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

Street address
Imam khomeini Ave

City
Isfahan

Province
Isfehan

Postal code
8195163381

Phone
+98 31 3386 6266

Email
heydari.pedres@gmail.com

Person responsible for updating data

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

Street address
Imam khomeini Ave

City
Isfahan

Province
Isfehan

Postal code
8195163381

Phone
+98 31 3386 6266

Email
heydari.pedres@gmail.com

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