

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jun 2026

The effect of nursing care training package on the duration of hospitalization and neonatal weight gain after surgery for gastrointestinal disorders

Protocol summary

Study aim

The effect of nursing care training package after gastrointestinal disorders surgery on length of hospital stay-neonatal weight gain

Design

Clinical trial has a control group with an intervention group, one-blind, non-randomized, on 60 patients

Settings and conduct

The present study will be performed on 30 infants in each group (control and intervention) in the neonatal intensive care unit of Akbar Hospital in Mashhad. This study will be done in two stages. In the first stage, the post-surgery care package for gastrointestinal abnormalities will be assembled based on a review of valid texts and under the supervision of experts. In the second stage, after obtaining permission from the university ethics committee, sampling of the control and intervention group will be done. During this phase, in addition to collecting clinical data, infants are monitored for weight gain and length of hospital stay. Individuals under study and analyst will be unaware of the intervention and control groups.

Participants/Inclusion and exclusion criteria

Informed consent of the parents, the infant with congenital gastrointestinal abnormalities (including esophageal atresia, intestinal atresia, closed anus of the infant) to the approval of the treating physician, the infant weighs more than 1500 grams at birth. The baby is 37 weeks old

Intervention groups

Intervention: Infants with congenital gastrointestinal disorders undergo reconstructive surgery, whose postoperative care will be based on a care package. Control: Infants with congenital gastrointestinal abnormalities undergo reconstructive surgery whose postoperative care is routinely performed.

Main outcome variables

-Duration of hospitalization from the time of admission until discharge -Weight gain baby

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201222049793N1**

Registration date: **2021-08-14, 1400/05/23**

Registration timing: **registered_while_recruiting**

Last update: **2021-08-14, 1400/05/23**

Update count: **0**

Registration date

2021-08-14, 1400/05/23

Registrant information

Name

Maryam Tavakolypolgerd

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 51 3678 7678

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-05-25, 1400/03/04

Expected recruitment end date

2021-09-26, 1400/07/04

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The effect of nursing care training package on the duration of hospitalization and neonatal weight gain after surgery for gastrointestinal disorders

Public title
Evaluation of the effects of nursing care training package on the duration of hospitalization and neonatal weight gain after surgery for gastrointestinal disorders in neonatal intensive care unit.

Purpose
Education/Guidance

Inclusion/Exclusion criteria
Inclusion criteria:
conscious parental consent Infant with congenital gastrointestinal abnormalities (including esophageal atresia, intestinal atresia, closed anus of the operated infant) in the hospital The baby weighs more than 1500 grams at birth. infant 37 weeks later
Exclusion criteria:
Occurrence of kidney-liver disease at the same time that makes it difficult to estimate the patient's weight.
Permanent transfer from hospital before discharge
Discharge from the hospital with personal consent before completing treatment

Age
From **8 months** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description
Participants (infants) in this study were blind.

Placebo
Not used

Assignment
Other

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Mashhad University of Medical Sciences

Street address

PhD Crossroads - School of Nursing and Midwifery

City

Mashhad

Province

Razavi Khorasan

Postal code

9491395512

Approval date

2020-07-24, 1399/05/03

Ethics committee reference number

lr.mums.nurse.rec.1399.026

Health conditions studied

1

Description of health condition studied

Imperforated Anus

ICD-10 code

K62.89

ICD-10 code description

Other specified diseases of anus

2

Description of health condition studied

Duodenal Atresia

ICD-10 code

K31.89

ICD-10 code description

Other diseases of duodenum

3

Description of health condition studied

Esophageal atresia

ICD-10 code

K22

ICD-10 code description

Other diseases of esophagus

Primary outcomes

1

Description

Comparison of the effect of nursing care training package on length of hospital stay and neonatal weight gain after gastrointestinal malignancy surgery

Timepoint

Measurement of hospitalization duration and neonatal weight gain after surgery until discharge in control and intervention groups

Method of measurement

Neonatal records and demographic information

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Infants with gastrointestinal abnormalities who have undergone reconstructive surgery and postoperative care based on a care package (in the field of surgical site care, respiratory care, and patient-related connections, nutritional care, correct positions and principles of position change, infection control, Blood care, excretory care) will be performed.

Category

Other

2

Description

Control group: : Infants with congenital gastrointestinal disorders undergo reconstructive surgery whose postoperative care will be routine.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

بیمارستان اکبر

Full name of responsible person

Rezaeian Aramesh

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Robabeh latif nejad

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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

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Tavakoly Polgerd Maryam

Position

student

Latest degree

Bachelor

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Latest degree

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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

Person responsible for updating data**Contact****Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

مریم توکلی پلگرد

Position

student

Latest degree

Bachelor

Other areas of specialty/work