

# 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)

##### Phone

+98 51 3678 7678

##### Email address

tavakolypm1@mums.ac.ir

##### 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

##### Street address

PhD Crossroads - School of Nursing and Midwifery

##### City

Mashhad

##### Province

Razavi Khorasan

##### Postal code

9491395512

##### Phone

+98 51 3856 1843

##### Email

rezaeianA@mums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Mashhad University of Medical Sciences

##### Full name of responsible person

Robabeh latif nejad

##### Street address

Doctora Crossroads - School of Nursing and Midwifery

##### City

mashhad

##### Province

Razavi Khorasan

##### Postal code

9491395512

##### Phone

+98 51 3859 1512

##### Fax

+98 51 3859 1512

##### Email

latifnejadr@mums.ac.ir

##### Web page address

https://www.mums.ac.ir

##### 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

##### Other areas of specialty/work

Nursery

##### Street address

Bolvar Razi 13

##### City

Darghaz

##### Province

Razavi Khorasan

##### Postal code

9491395512

##### Phone

+98 51 3859 1511

##### Email

tavakolypm1@mums.ac.ir

## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

rezaeian aramesh

**Position**

هیئت علمی

**Latest degree**

Master

**Other areas of specialty/work**

Nursery

**Street address**

Doctora Crossroads - School of Nursing and Midwifery

**City**

mashhad

**Province**

Razavi Khorasan

**Postal code**

9491395512

**Phone**

+98 51 3859 1512

**Fax**

+98 51 3859 1512

**Email**

rezaeiana@mums.ac.ir

**Web page address**

<https://www.mums.ac.ir>

Nursery

**Street address**

Doctora Crossroads - School of Nursing and Midwifery

**City**

mashhad

**Province**

Razavi Khorasan

**Postal code**

9491395512

**Phone**

+98 51 3859 1512

**Email**

tavakolypm1@mums.ac.ir

**Web page address**

<https://www.mums.ac.ir>

**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**