

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

In ward reduction compared with traditional reduction under general anesthesia in gastroschisis neonates (short term result)

Protocol summary

Summary

The purpose of this non-randomized, multicenter trial is to compare reduction of abdominal contents of neonates with Gastroschisis in ward without general anesthesia and in operating room under general anesthesia. A total of 30 neonates born with Gastroschisis will be studied in pediatric centers of Shaheed Beheshti, Tabriz, Mashhad, Qazvin, and Shiraz Medical Universities. For the neonates in the first group, immediately after admission in the centers and initial Supportive treatment, abdominal contents are reduced in the ward without the use of general anesthesia while for the second group the abdominal contents are reduced with conventional technique in the operating room under general anesthesia. Hospitalization period, NICU stay, the need for ventilator and anesthesia, the later need for any surgical procedure, duration of receiving TPN and complete intestinal nutrition will be compared between the two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201012085342N1**
Registration date: **2011-04-23, 1390/02/03**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2011-04-23, 1390/02/03

Registrant information

Name

Kamrooz Pouryousef

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 1334 1317

Email address

pouryousefk@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Tabriz University of Medical Sciences

Expected recruitment start date

2010-05-22, 1389/03/01

Expected recruitment end date

2012-05-21, 1391/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

In ward reduction compared with traditional reduction under general anesthesia in gastroschisis neonates (short term result)

Public title

Comparison of reduction of abdominal content in the ward with reduction under general anesthesia in the operating room in neonates with gastroschisis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: neonates born with gastroschisis
Exclusion criteria: presence of major anomalies, peritonitis, intestinal atresia

Age

To **30 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 30

Randomization (investigator's opinion)

Not randomized

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

Tabriz University Of Medical Sciences and Health Services

Street address

Golgasht Ave.

City

Tabriz

Postal code

Approval date

2011-01-30, 1389/11/10

Ethics committee reference number

8957/4/5

Health conditions studied

1

Description of health condition studied

Gastroschisis

ICD-10 code

Q79.3

ICD-10 code description

Gastroschisis

Primary outcomes

1

Description

Duration of receiving TPN

Timepoint

During hospitalization

Method of measurement

Time to beginning of entral feeding, in days

2

Description

Time to onset of entral feeding

Timepoint

During hospitalization

Method of measurement

time to discontinuation of TPN in days

3

Description

Need for further surgical procedure

Timepoint

During hospitalization

Method of measurement

Undergoing any surgical procedure

4

Description

Hospital stay

Timepoint

admission and discharge

Method of measurement

in days

5

Description

NICU stay

Timepoint

Admission in and transfer from neonatal ward

Method of measurement

in days

6

Description

Need for ventilation and its duration

Timepoint

connection to ventilator and Out of ventilator

Method of measurement

in days

7

Description

Need for general anesthesia under reduction

Timepoint

During the intervention

Method of measurement

Receiving general anesthesia

Secondary outcomes

1

Description

Saving in health facilities

Timepoint

During the study

Method of measurement

Reduction the use of facilities

2

Description

Reduce costs

Timepoint

at end of study

Method of measurement

calculation of costs

Intervention groups

1

Description

Control group: Reduction of abdominal contents in the operating room under general anesthesia with conventional technique

Category

Treatment - Surgery

2

Description

Intervention group: Reduction of abdominal contents in the neonatal ward without general anesthesia

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Children's Hospital Of Tabriz

Full name of responsible person

Dr. Saeed Aslanabadi, Associate Professor of Pediatric Surgery

Street address

Sheshglan Ave.

City

Tabriz

2

Recruitment center

Name of recruitment center

Pediatric Education and Treatment Center Of Shahid Beheshti University Of Medical Sciences and Health

Full name of responsible person

Dr. Ahmad Khalegh Nejad Tabari, Professor of Pediatric Surgery

Street address

City

Tehran

3

Recruitment center

Name of recruitment center

Children's Hospital Of Shiraz

Full name of responsible person

Dr. Hamid Forotan, Professor Of Pediatric Surgery

Street address

City

Shiraz

4

Recruitment center

Name of recruitment center

Children's Hospital Of Mashhad

Full name of responsible person

Dr. Mehran Hiradfar, Associate Professor of Pediatric Surgery

Street address

City

Mashhad

5

Recruitment center

Name of recruitment center

Children's Hospital Of Gazvin

Full name of responsible person

Dr. Saeed Tarlan- Associate Professor Of Pediatric Surgery

Street address

City

Gazvin

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz Medical University Of sciences and Health Services

Full name of responsible person

Miss Magami

Street address

Research Center of Medicine Faculty, Golgasht Ave.

City

Tabriz

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tabriz Medical University Of sciences and Health Services

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Tabriz University Of Medical Sciences and Health Services

Full name of responsible person

Dr. Kamrooz Pouryousef

Position

Resident Of General Surgery

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Full name of responsible person

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Postal code**Phone**

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty