Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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 Healt
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 scienes 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 scienes 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
Rezident Of General Surgery

Other areas of specialty/work

Street address
General Surgery Groap, Imam Reza Hospital - Golgasht Ave.

City
Tabriz

Postal code

Phone
+98 41 1334 1317

Fax
+98 41 1334 1317

Email
pouryousefk@tbzmed.ac.ir

Web page address

Person responsible for scientific 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

Other areas of specialty/work

Street address
Imam Reza Hospital ,Golgasht Ave.

City
Tabriz

Postal code

Phone
+98 41 1334 1317

Fax
+98 41 1334 1317

Email
pouryousefk@tbzmed.ac.ir

Web page address
www.tbzmed.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Full name of responsible person
Kamrooz Pouryousef

Position
Resident Of General Surgery

Other areas of specialty/work

Street address
Imam Reza Hospital, Golgasht Ave.

City
Tabriz

Postal code

Phone
+98 41 1334 1317

Fax
+98 41 1334 1317

Email
pouryousefk@tbzmed.ac.ir

Web page address

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