

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jun 2026

A comparative study of complications in single stage with triple stage conventional repair of imperforated anus disease in female neonates in Kermanshah

Protocol summary

Summary

This study is a blind, randomized clinical trial. The purpose of this study is comparison between complications of two methods of surgery (single stage and conventional triple stage) in repair of imperforated anus with rectovestibular fistula in female infants who are candidates for surgical repair in Imam Reza hospital of Kermanshah. The patients with acute obstruction are excluded from this study. A total of 60 patients are randomly allocated to two groups of intervention. In first group (single stage surgery) patients after primary preparations will undergo Posterior Sagittal Anorectoplasty procedure. In second group (conventional triple stage surgery) at first stage, patients will undergo colostomy fitting procedure and then at second stage, a Posterior sagittal Anorectoplasty will be done and at third stage, the fitted colostomy will be closed. Both groups will be followed at first week, first month, third month and sixth month after surgery and complications (wound infection, anus stenosis and vaginal trauma) will be compared.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201204239547N1**
Registration date: **2012-10-23, 1391/08/02**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-10-23, 1391/08/02

Registrant information

Name

Saman Ketabchian

Name of organization / entity

Kermanshah University of Medical Science

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

Kermanshah University of Medical Science

Expected recruitment start date

2011-03-21, 1390/01/01

Expected recruitment end date

2013-03-21, 1392/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparative study of complications in single stage with triple stage conventional repair of imperforated anus disease in female neonates in Kermanshah

Public title

Study of single stage with triple stage conventional repair of imperforated anus

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: all female children under one year old with diagnosis of imperforated anus and rectovestibular fistula. Exclusion criteria: urgent circumstances such as

acute obstruction and dissatisfaction of parents with single stage procedure.

Age

To **1 year** old

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Patients will be divided randomly (an in-between) into two intervention groups equally without awareness of surgeon.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Kermanshah University of Medical Sciences

Street address

Vice Chancellor for research, Kermanshah University of Medical Sciences, Shahid Beheshti Blvd., Kermanshah

City

Kermanshah

Postal code

Approval date

2012-04-17, 1391/01/29

Ethics committee reference number

7/420/1364/پ

Health conditions studied

1

Description of health condition studied

Imperforated anus

ICD-10 code

Q42.2

ICD-10 code description

Congenital absence, atresia and stenosis of anus with

fistula

Primary outcomes

1

Description

Wound infection

Timepoint

A week after procedure

Method of measurement

Surgeon diagnosis

2

Description

Anus stenosis

Timepoint

One and three and six months after surgery

Method of measurement

Surgeon diagnosis

3

Description

Vaginal trauma

Timepoint

During procedure

Method of measurement

Surgeon diagnosis

Secondary outcomes

empty

Intervention groups

1

Description

In single stage group without fitting a colostomy, only a Posterior Sagittal Anorectoplasty (repair of fistula and reconstruction of anus) is done.

Category

Treatment - Surgery

2

Description

In triple stage group the intervention is fitting an end sigmoid colostomy with laparotomy at first stage and then at second stage Posterior Sagittal Anorectoplasty (repair of fistula and reconstruction of anus) is done and at third stage, the fitted colostomy will be closed after two months with laparotomy.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza hospital of Kermanshah

Full name of responsible person

Saman Ketabchian

Street address

Imam Reza hospital, Parastar Blvd., Kermanshah

City

Kermanshah

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Kermanshah University of Medical Sciences

Full name of responsible person

Farid Najafi

Street address

Vice chancellor for research, Kermanshah University of Medical Sciences, Shahid Beheshti Blvd., Kermanshah University of Medical Sciences

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Kermanshah

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research, Kermanshah University of Medical Sciences

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

Kermanshah University of Medical Sciences

Full name of responsible person

Saman Ketabchian

Position

Resident of general surgery

Other areas of specialty/work

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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