

# 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)

##### Phone

+98 83 1427 6312

##### Email address

dr.s.ketabchian@kums.ac.ir

##### 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 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

**City**

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****Street address**

General surgery ward, Imam Reza hospital, Kermanshah

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## Person responsible for scientific inquiries

### Contact

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**Full name of responsible person**

Omid Amanollahi

**Position**

Pediatric surgeon

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## Person responsible for updating data

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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*