A comparative study of sutureless circumcision and conventional circumcision with suture

Protocol summary

Summary
This study is a single blind, randomized clinical trial. The purpose of this study is comparison between complications of conventional surgical circumcision without sutures and with sutures in children referred to Imam Reza hospital of Kermanshah. 100 patients were randomized into two groups, circumcision Procedure without stitches and conventional. Inclusion criteria is all children referred for circumcision to Imam Reza hospital. The group operates without using sutures, after removing the foreskin and mucosal cuff, after sufficient hemostasis operation completed. In group with suture by using absorbable string, foreskin and mucosal cuff approximate. Patients in both groups will be followed for first week and first month, and will examine the effects of bleeding and infection. Data from the two groups will be compared in the study.

General information

Acronym
IRCT registration information
IRCT registration number: IRCT2013020512368N1
Registration date: 2013-06-18, 1392/03/28
Registration timing: retrospective

Recruitment status
Recruitment complete
Funding source
Kermanshah University of Medical Sciences

Expected recruitment start date
2011-03-21, 1390/01/01
Expected recruitment end date
2012-03-20, 1391/01/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
A comparative study of sutureless circumcision and conventional circumcision with suture

Public title
comparison between two methods of circumcision

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: Children referred for circumcision to Imam Reza Hospital. Exclusion criteria: Children whose parents did not consent to circumcision procedure without suture.

Age
To 12 years old

Gender
Male

Phase
N/A

Groups that have been masked
Sample size
Target sample size: 100

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description
Not used

Assignment
Parallel

Other design features

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, Kermansha University of Medical Sciences, Shahid Beheshti Blvd, Kermanshah
City
Kermanshah
Postal code

Approval date
2012-08-08, 1391/05/18

Ethics committee reference number
7/420/19129/

Health conditions studied

1
Description of health condition studied
Circumcision
ICD-10 code
Z41.2
ICD-10 code description
Routine and ritual circumcision

Primary outcomes

1
Description
bleeding
Timepoint
One week and one month after surgery
Method of measurement
Surgeon diagnosis

2
Description
Infection
Timepoint
One week and one month after surgery
Method of measurement
Surgeon diagnosis

3
Description
Inflammation
Timepoint
One week and one month after surgery
Method of measurement
Surgeon diagnosis

Secondary outcomes
empty

Intervention groups

1
Description
In circumcision surgery without sutures, the string is not used to repair.
Category
Treatment - Surgery

2
Description
In conventional surgical technique, Absorbable suture to approximate the foreskin and mucosal cuff is used.
Category
Treatment - Surgery

Recruitment centers

1
Recruitment center
Name of recruitment center
Imam Reza hospital of Kermanshah
Full name of responsible person
Ardalan Solimani
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
empty

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
Ardalan Solimani

Position
Resident of General Surgery

Other areas of specialty/work

Street address
General Surgery ward, Imam Reza hospital, Kermanshah

City
Kermanshah

Postal code

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+98 83 1427 6311

Fax

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ardalansolimani@yahoo.com

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