

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Determination of clinical and laboratory results obtained from the use of two different wraps in reducing the number and size of polyps in patients with bladder exstrophy using these plastic wraps

Protocol summary

Summary

Objective: The aim of this study was to assess the role of high-barrier plastic wraps in reducing polyps' size and number, as well as decreasing the inflammation and allergic reactions in bladder exstrophy cases. Design: Eight patients with bladder exstrophy-epispadias complex (BEEC) that used a low density polyethylene (LDPE) for coverage of the exposed polypoid bladder in preoperative care management were referred to our center. These patients used a high-barrier wrap made of polyvinylidene chloride (PVdC) until the time of closure. The new wrap was applied for an average duration of 1 year before surgery. Polyp size and number, incidence of para-exstrophy skin infection/inflammation, and skin allergy were assessed every 2 months. Biopsies were taken from the polyps to identify histopathological characteristics of the exposed polyps. The characteristics of the wraps were also evaluated by Fourier transform infrared spectroscopy (FTIS), scanning electron microscopy (SEM), evaporation tests, and bacterial culture tests. Results: Polyps' size and number decreased in patients after the application of a high-barrier wrap after 12 months. There was no allergic reaction in patients after the usage of PVdC. Moreover, none of the patients developed pre-malignant changes in histopathological examinations after 12 months. PVdC had higher integrity and smaller pores in SEM. Evaporation and penetration tests were also more satisfactory in PVdC Conclusion: Polyps' size, number, and morbidity may significantly decrease by applying a high-barrier wrap. Certain PVdC wraps (Saran wraps) with more integrity and less evaporative permeability may be more "exstrophy-friendly."

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201611268554N2**

Registration date: **2017-04-23, 1396/02/03**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-04-23, 1396/02/03

Registrant information

Name

Abdol-mohammad Kajbafzadeh

Name of organization / entity

pediatric urology and reconstructive medicine
research center

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2016-11-06, 1395/08/16

Expected recruitment end date

2017-06-21, 1396/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Determination of clinical and laboratory results obtained from the use of two different wraps in reducing the number and size of polyps in patients with bladder exstrophy using these plastic wraps

Public title

The use of two different wraps in reducing the number and size of polyps in patients with bladder exstrophy

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Children with bladder exstrophy and simultaneous bladder polyps; children in whom LDPE wrap with low permeability was applied before entering the study; children with obtained informed consent from parents in pediatric urology research center
Exclusion criteria: Children with bladder exstrophy and simultaneous bladder polyps who use PVDC wrap before entering the study; children in whom informed consent was not obtained from parents

Age

From **1 day** old to **13 years** old

Gender

Male

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **10**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Single blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Tehran University of Medical Sciences

Street address

: No. 62, Dr. Qarib's Street, Keshavarz Boulevard

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Postal code

1419433151

Approval date

2016-05-18, 1395/02/29

Ethics committee reference number

IR.TUMS.REC.1395.2614

Health conditions studied**1****Description of health condition studied**

Bladder exstrophy

ICD-10 code

Q64.1

ICD-10 code description

Exstrophy of urinary bladder

Primary outcomes**1****Description**

Number of polyps

Timepoint

During the study

Method of measurement

Counting

2**Description**

Size of polyps

Timepoint

During the study

Method of measurement

Measure with ruler

Secondary outcomes**1****Description**

Number of polyps

Timepoint

In the end of study

Method of measurement

Counting

2**Description**

Size of polyps

Timepoint

In the end of study

Method of measurement

Measure with ruler

Intervention groups**1****Description**

At birth, the sensitive exposed bladder mucosa should be covered with a non-adherent film (Plastic Wrap) (PVDC)

to prevent infection and sticking of the bladder to
diapers or clothing.

Category

Treatment - Other

2

Description

At birth, the sensitive exposed bladder mucosa should be covered with a non-adherent film (Plastic Wrap) (LDPE) to prevent infection and sticking of the bladder to diapers or clothing.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Children's Hospital Medical Center

Full name of responsible person

Street address

City

tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Miss Norouzzadeh

Street address

Floor 6. Ghods Street, Keshavarz Boulevard

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Mohammadjavad Mohseni

Position

MD, Manager Pediatric Urology And Regenerative
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Other areas of specialty/work

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Person responsible for scientific inquiries

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full professor pediatric Urology

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Position

Manager

Other areas of specialty/work

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Fax
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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