Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of treatment outcomes between endoscopic injection of new bulking agent of Vantris® and open surgery of Gil-vernet in 1-10 year-aged children with primary vesicoureteral reflux(VUR)

Protocol summary

Summary

The objective is to compare the results of treatment of primary VURs using single injection of Vantris with Gil-Vernet open surgery in 1-10 years old children. 100 renal units involved with VUR in a randomized clinical manner were included in this study. VUR is diagnosed and graded using VCUG. VURs with grade II to IV are the target patients. Other grades of VUR, anatomic abnormalities, neurogenic bladder and previous surgeries on lower urinary tract are excluded from the study. Follow-up VCUG is to be done after 3 months. the surgical efficacy is defined as a decrease or resolution of VUR seen at VCUG.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015022321211N1**
Registration date: **2015-04-24, 1394/02/04**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2015-04-24, 1394/02/04

Registrant information

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Health curriculum (of Health Ministry)

Expected recruitment start date

2013-08-22, 1392/05/31

Expected recruitment end date

2016-03-19, 1394/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of treatment outcomes between endoscopic injection of new bulking agent of Vantris® and open surgery of Gil-vernet in 1-10 year-aged children with primary vesicoureteral reflux(VUR)

Public title

Comparison of treatment outcomes between endoscopic injection of new agent of Vantris® and open surgery of Gil-vernet in 1-10 year-aged children with primary vesicoureteral reflux

Purpose

Treatment

Inclusion/Exclusion criteria

Iinclusion criteriae: 1)1-10 years of old ; 2) II to IV grade VURs, as defined below: a) Symptomatic UTIs(such as fever,dysuria,poor feeding, FTT); New renal scarring despite of antibiotic prophylaxis; bilateral VUR; Intolerance to prophylactic antibiotics; parent tendency to surgical repair. Exclusion criteriae: 1)Grades I and V ; 2) previously open or endoscopic surgeries on bladder or ureters ; 3) Anantomic malformations of urinary tract

such as obstructive disorders or complete duplication of pyelocaliceal system ; 4)suspicion to or confirmed voiding disorder : a. presence of related clinical findings including abnormal neurologic exam or elimination disorder(instinal and urinary, with together); b.VCUG or ultrasonographic abnormalities such as bladder wall abnormalities or diverticuli ortrabeculation or decreased vesical capacity ; 5)Neurogenic bladder

Age

From **1 year** old to **10 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

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

the Vice Chancellor for Research (VCR) of Tabriz University of Medical Sciences (TUOMS

Street address

International Relations Office, No 2 Central Building, Tabriz University of Medical Sciences, Golgasht street,University Street, PO Box: 516566593

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Tabriz

Postal code

Approval date

2015-02-08, 1393/11/19

Ethics committee reference number

5/4/10953

Health conditions studied

1

Description of health condition studied

Vesicouretral reflux

ICD-10 code

Q62.7

ICD-10 code description

Congenital vesico-uretero-renal reflux

Primary outcomes

1

Description

Grade of VUR

Timepoint

3 months

Method of measurement

Grading system for VUR on VCUG,)International Reflux Study Committee)

Secondary outcomes

1

Description

Unimproved VUR

Timepoint

3 months

Method of measurement

Grading system for VUR on VCUG,)International Reflux Study Committee)

Intervention groups

1

Description

Control: Gil-vernet open surgery ;The ureteral orifices are advanced across the trigone by means of a single submucosal mattress suture in order to increase the intramural length and muscular support of each distal ureter.

Category

Treatment - Surgery

2

Description

Intervention: Endoscopic Vantris; In patients with grade I-III VUR, the usual technique of subureteric transurethral injection, with the needle is to be introduced submucosally under the ureteral orifice at the 6 o’clock position'using cystocopes 6 Fr and needles 3.7 Fr. in those with a widely open orifice, the injection is to be performed inside the orifice,as needed.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Reza and Children Hospital

Full name of responsible person
Dr Fahimeh Kazmi Rashed
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Sheshgelan street, Tabriz Children Hospital
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor Of Research Of Tabriz University Of Medical Sciences
Full name of responsible person
Dr.Mohammad Reza Rashidi, Vice Chancellor Of Research
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3rd floor ,No 10, Faculty Of Medicine,Golgasht street, Vice Chancellor Of Research
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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
Vice Chancellor Of Research Of Tabriz 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

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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