

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 Jul 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

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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.

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

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

Name

M. Reza Roshandel

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Email address

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

Inclusion 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) Anatomic 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 (intestinal and urinary, with together); b.VCUG or ultrasonographic abnormalities such as bladder wall abnormalities or diverticuli or trabeculation 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

City

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 cystoscopes 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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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

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Full name of responsible person

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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**Contact****Name of organization / entity**

Tabriz Univercity Of Medical Scinces

Full name of responsible person

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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