

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The effect of autologous peripheral blood cells transplantation along with platelet rich plasma in the treatment of patients with vesicoureteral reflux

Protocol summary

Study aim

Evaluation of efficacy and side effects of injection, peripheral blood cells with platelet growth factors in treatment of urinary reflux

Design

A total of 17 patients with vesicourethral reflux who met our inclusion criteria, were evaluated. the study performed without control group and blindness. 17 patients included for phase-1 trial. Endoscopic injection was made by one surgeon in all patients in 6 o'clock and 0.5 cm away from the ureteral orifice. They were followed by renal ultrasonography and radiologic VCUG at 3 and 18 months after the injection . The success of the injection was determination of no VUR on the following VCUGs. If the VUR persisted, the second injection was performed 3 months after the first one

Settings and conduct

Patients undergo stem cell injection in the operating room. The patient has a urethra catheter and a double j catheter. The next day the urethra catheter is removed. And 45 days later the double j catheter is removed. Then the treatment response is measured 3 and 6 months later by sonography, U/C, U/A and cystography. Re-injections will be needed in specific cases and a thoughtful treatment response will be provided. the study set in Imam-Reza hospital in Mashhad, Iran.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patient with reflux grade 2, 3 or 4 grade
No surgical treatment has been performed so far
Exclusion criteria: The patient is in the acute phase of urinary tract infection
Patient with renal failure due to reflux
Patient with grade 1 or 5 reflux

Intervention groups

Patients diagnosed with vesicourethral reflux, undergo stem cell injection in the vesicourethral junction.

Main outcome variables

vesicourethral reflux cure

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170417033489N4**

Registration date: **2020-04-28, 1399/02/09**

Registration timing: **retrospective**

Last update: **2020-04-28, 1399/02/09**

Update count: **0**

Registration date

2020-04-28, 1399/02/09

Registrant information

Name

Salman Soltani

Name of organization / entity

Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 51 3802 2553

Email address

soltanis@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2011-10-22, 1390/07/30

Expected recruitment end date

2015-10-22, 1394/07/30

Actual recruitment start date

2014-05-22, 1393/03/01

Actual recruitment end date

2016-01-01, 1394/10/11

Trial completion date

2016-09-10, 1395/06/20

Scientific title

The effect of autologous peripheral blood cells transplantation along with platelet rich plasma in the treatment of patients with vesicoureteral reflux

Public title

The effect of autologous peripheral blood cells transplantation along with platelet rich plasma in the treatment of patients with vesicoureteral reflux

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patient with re flux grade 2, 3 or 4 grade No surgical treatment has been performed so far

Exclusion criteria:

The patient is in the acute phase of urinary tract infection Patient with renal failure due to re flux Patient with grade 1 or 5 re flux

Age

From **15 years** old to **35 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **15**

More than 1 sample in each individual

Number of samples in each individual: **1** re injection

Actual sample size reached: **17**

More than 1 sample in each individual

Actual sample size in each individual: **1** bilateral vesicoureteral reflux

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mashhad University of Medical Sciences

Street address

Bahar Street

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913316

Approval date

2635-07-07, 2014/04/16

Ethics committee reference number

Ethics committee of Mashhad University of Medical Sciences

Health conditions studied

1

Description of health condition studied

Vesicoureteral reflux

ICD-10 code

N13.7

ICD-10 code description

Vesicoureteral-reflux

Primary outcomes

1

Description

Reflux Grade

Timepoint

Determination of urinary reflux grade at baseline, three and six months after intervention

Method of measurement

Ultrasound, Cystography, U/A, U/C

Secondary outcomes

empty

Intervention groups

1

Description

This study aimed to evaluate the therapeutic efficacy of endoscopic subureteric injection of autologous peripheral blood cells along with platelet-rich plasma. Each injection contained whole blood cells with platelet growth factors derived from the peripheral blood of the patient. The blood were collected and sent to specialized laboratories for the isolation of peripheral blood cells and platelet growth factor preparation. the resultant material injected endoscopically into the subureteric region of the bladder.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital of Mashhad

Full name of responsible person

Dr Maliheh Keshvari Shirvan

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Bahar Street

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+98 51 3858 3885

Email

keshvarim@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

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

Mashhad University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Maliheh Keshvari Shirvan

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

Urology

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Maliheh Keshvari Shirvan

Position

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Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Maliheh Keshvari Shirvan

Position

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Latest degree

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Other areas of specialty/work

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No more information to declare

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

patients information are shareable after making them anonymous

When the data will become available and for how long

6 months after publication

To whom data/document is available

all

Under which criteria data/document could be used

medicine-related researchers

From where data/document is obtainable

Dr.Maliheh Keshvari

What processes are involved for a request to access data/document

Send an email to conductor

Comments