

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

A clinical trial to compare the effectiveness of peripheral blood mononuclear cell (PBMC) with platelet rich plasma in vesicoureteral reflux patients before and after treatment

Protocol summary

Study aim

To compare the effectiveness of peripheral blood mononuclear cell (PBMC) with platelet rich plasma in vesicoureteral reflux patients before and after treatment.

Design

A before after, community-based clinical trial including 20 patients suffering from vesicoureteral reflux

Settings and conduct

The study population will be selected from the patients with vesicoureteral reflux referring to Imam Reza Hospital, Mashhad, Iran, and will be administered peripheral blood mononuclear cell with platelet rich plasma for treatment.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age less than 14 years old; grade 1 to 4 of vesicoureteral reflux; having indication for surgical intervention such as repeated pyelonephritis or creation of new scars in renal nuclear scan. Exclusion criteria: Urinary tract infection; Secondary vesicoureteral reflux; reflux grading 5; history of anti-reflux surgery.

Intervention groups

The intervention group will receive 5 cc peripheral blood mononuclear cell with platelet rich plasma that has been taken from each patient him/her-self and has been prepared.

Main outcome variables

The status and grade of reflux

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190117042391N1**

Registration date: **2019-02-15, 1397/11/26**

Registration timing: **prospective**

Last update: **2019-02-15, 1397/11/26**

Update count: **0**

Registration date

2019-02-15, 1397/11/26

Registrant information

Name

Amin Mirsani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3854 3031

Email address

mirsania9411@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-02-20, 1397/12/01

Expected recruitment end date

2020-02-20, 1398/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A clinical trial to compare the effectiveness of peripheral blood mononuclear cell (PBMC) with platelet rich plasma in vesicoureteral reflux patients before and after treatment

Public title

The treatment of patients with vesicoureteral reflux

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age less than 14 years old Grade 1 to 4 of vesicoureteral reflux Having indication for surgical intervention such as repeated pyelonephritis or the creation of new scars in the renal nuclear scan

Exclusion criteria:
Urinary tract infection Reflux grade 5 Secondary vesicoureteral reflux History of anti-reflux surgery

Age
To **14 years** old

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **20**

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
Vice Chancellor for Research, Mashhad University of Medical Sciences, Ghoreishi building, Daneshgah Street

City
Mashhad

Province
Razavi Khorasan

Postal code
9195965919

Approval date
2018-10-02, 1397/07/10

Ethics committee reference number
IR.MUMS.REC.1397.252

Health conditions studied

1

Description of health condition studied
Vesicoureteral reflux

ICD-10 code
N13.7

ICD-10 code description
Vesicoureteral-reflux-associated uropathy

Primary outcomes

1

Description
The status and grade of reflux

Timepoint
Before and 3 months after intervention.

Method of measurement
Cystography

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: this group will receive 5 cc peripheral blood mononuclear cell with platelet rich plasma that has been taken from each patient him/her-self and has been prepared.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Imam Reza Hospital

Full name of responsible person
Amin Mirsani

Street address
Imam Reza Hospital, Imam Reza Square

City
Mashhad

Province
Razavi Khorasan

Postal code
9137913316

Phone
+98 51 3854 3031

Email
Mirsania941@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaghodi

Street address

Imam Reza Hospital, Imam Reza Square

City

Mashhad

Province

Razavi Khorasan

Postal code

913753459

Phone

+98 51 3841 1538

Email

vcresearch@mums.ac.ir

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

Amin Mirsani

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Urology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Amin Mirsani

Position

Resident

Latest degree

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be 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

Not applicable

Title and more details about the data/document

Information on the main outcome or the like can be shared.

When the data will become available and for how long

6 months after printing results

To whom data/document is available

Our data will only be available to researchers working at science centers and universities.

Under which criteria data/document could be used

Our data will be available for scholars working at science centers and universities.

From where data/document is obtainable

Amin Mirsani provides the data analysis to the applicants via email: Mirsania941@mums.ac.ir

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

Applicants can respond to the email of the respondent and receive a response within a week.

Comments