Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of donor bone marrow cells infusion on chimerism and prognosis of kidney allograft outcomes.

Protocol summary

Summary

Infusion of donor CD34+progenitor cells concurrent with organ transplantation is one the most effective protocols for induction and/or augmentation of post-transplant chimerism. The aim of our study was to investigate the effect of donor bone marrow cells infusion (DBMI) on chimerism augmentation and outcome of allograft in renal transplant recipients from living unrelated donors (LURD). A randomized controlled trial, without placebo, not blinded and single center study was performed on 40 kidney allograft recipients consisted of 20 patients with DBMI (100-150 ml of isolated mononuclear cells from donor bone marrow sample) and 20 patients without infusion; the patients were monitored prospectively for two year. Informed consent was obtained from all donors and recipients according to protocols approved by Tehran University of Medical Sciences Ethics Committee. Inclusion criterion was: being the case for first renal transplantation and exclusion criteria were: having genetic, cardiovascular diseases; previous transfusion, re-transplantation and morbid obesity. Both groups received the same baseline immunosuppressant; consist of triple drug regimen; cyclosporine A, mycophenolate mofetil (MMF) and prednisolone. Primary outcomes were the content of post-transplant microchimerism and its relation with acute rejection episodes and allograft function. Secondary outcomes were the presence of anti-HLA antibodies, serum levels of sCD30, IFN-γ and IL-10 and their association with clinical manifestation and microchimerism levels during two years follow-up period.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201106266876N1**
Registration date: **2011-06-27, 1390/04/06**
Registration timing: **retrospective**
Last update:
Update count: **0**

Registration date

2011-06-27, 1390/04/06

Registrant information

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Tehran University of Medical Sciences

Expected recruitment start date

2006-01-01, 1384/10/11

Expected recruitment end date

2008-01-01, 1386/10/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of donor bone marrow cells infusion on chimerism and prognosis of kidney allograft outcomes.

Public title

The role of chimerism in organ transplantation

Purpose

Prevention

Inclusion/Exclusion criteria
Inclusion criteria: Being the case of first renal transplantion Exclusion criteria: Previous transfusion; retransplantation; cardiovascular diseases; having genetic diseases and morbid obesity.
Age
From **25 years** old to **55 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **40**
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 Ethics Committee, Tehran University of Medical Sciences
Street address
Ghods st., Keshavarz blv.
City
Tehran
Postal code
Approval date
2005-03-10, 1383/12/20
Ethics committee reference number
2023

Health conditions studied

1

Description of health condition studied
Kidney allograft recipients
ICD-10 code
N19
ICD-10 code description
Unspecified renal failure

Primary outcomes

1

Description
Serum creatinine levels
Timepoint
Weekly in first 3 month and then monthly during two years follow-up
Method of measurement
Colorimetric method (Jaffe)

2

Description
Microchimerism quantification
Timepoint
Weeks: 1 and 2; months: 1, 3, 6 and 12
Method of measurement
Real-time PCR

3

Description
Acute rejection episodes
Timepoint
During 6 months after transplantation
Method of measurement
Clinical evaluation and biopsy protocol

Secondary outcomes

1

Description
sCD30
Timepoint
Days: 4, 14 and 30 after transplant
Method of measurement
ELISA method

2

Description
Anti-HLA antibodies
Timepoint
Second week; months: 1 and 3
Method of measurement
ELISA method

3

Description
Sera cytokines (IL-10 and IFN-g)
Timepoint
Days: 10 and 14 after transplant
Method of measurement
ELISA method

Intervention groups

1

Description

The intervention group: 20 patients who received donor bone marrow cells infusion concurrent with their kidney allograft (DBMI group). triple drug regimen for all patients include cyclosporine A (6mg/kg/day BD), mycophenolate mofetil (MMF) (2 gr/day BD) and prednisolone (2 mg/kg/day). Donor bone marrow cells were obtained from iliac crest by aspiration of 150-200 milliliters of bone marrow specimen at the time of donor nephrectomy. Afterwards, mononuclear cells of those samples were isolated using hydroxyethyl starch (HES 6%). One-half ml aliquots of MNCs suspension in HES were analyzed for absolute count of total nucleated cells, and flowcytometric determination of percentage and absolute number of CD34+ CD45+ hematopoietic progenitor cells . The average volume of donor cells which infused immediately post-operatively was 100-150 ml of mononuclear cells / recipient.

Category

Other

2

Description

The control group: 20 patients who received kidney allograft only. triple drug regimen for all patients include cyclosporine A (6mg/kg/day BD), mycophenolate mofetil (MMF) (2 gr/day BD) and prednisolone (2 mg/kg/day).

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Sina hospital, Tehran University of Medical Sciences

Full name of responsible person

Dr. Gholamreza Pourmand

Street address

Urology research center, Sina hospital, Imam khomeini str.

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Tehran University of Medical Sciences

Full name of responsible person

Dr. Akbar Fotouhi

Street address

Ghods St., Keshavarz Blv.

City

Tehran

Grant name

Grant code / Reference number

2023

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

Yes

Title of funding source

Vice chancellor for research, 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

Immunology dept, School of medicine, AJUMS, Ahvaz, Iran

Full name of responsible person

Dr. Ghasem Solgi

Position

Assistant professor

Other areas of specialty/work

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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