Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 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

Name
Ghasem Solgi
Name of organization / entity
AJUMS
Country
Iran (Islamic Republic of)
Phone
+98 61 1374 8747
Email address
solgi@razi.tums.ac.ir

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

Street address
Immunology dept, School of medicine, AJUMS, Golestan st., Ahvaz, Iran

City
Ahvaz

Postal code

Phone
+98 61 1374 8747

Fax

Email
solgi@razi.tums.ac.ir ghsolgi2@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Molecular Immunology Research Center, Tehran University of Medical Sciences

Full name of responsible person
Dr. Ali Akbar Amirzargar

Position
Professor

Other areas of specialty/work

Street address
Building No.7, School of medicine, Poursina Ave

City
Tehran

Postal code

Phone
+98 21 6443 2465
Fax
+98 21 6641 9536
Email
amirzara@sina.tums.ac.ir
Web page address

Person responsible for updating data

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
Street address
Immunology Dept, School of medicine, AJUMS, Golestan str.
City
Ahvaz
Postal code
Phone
Fax
Email
ghsolgi2@yahoo.com
Web page address

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