

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Evaluation of the outcomes and complications of use of extended carotid artery with Y-graft technique versus conventional Y-graft technique in pancreatic transplant surgery in the treatment of type 1 diabetic patients; A prospective randomized controlled trial

Protocol summary

Study aim

To study a specific arterial reconstruction policy for pancreatic transplants and its outcome

Design

A therapeutic clinical trial with the control group, not blinded, randomized, on 60 patients. Samples are randomly allocated into two groups using random allocation software 2.0.

Settings and conduct

In this therapeutic RCT, samples are selected by available sampling method from patients with type 1 diabetes who require SPK transplantation. Samples will be divided into intervention (n=30) and control (n=30) groups by simple randomization. Two different techniques for SPK transplantation in these patients at Abu Ali Sina Transplant Hospital in Shiraz are studied and compared in terms of results and complications.

Participants/Inclusion and exclusion criteria

-Inclusion criteria: Patient's consent Pancreas transplant form Having a simultaneous pancreas-kidney (SPK) transplant Patients with diabetic nephropathy who undergo portal venous drainage Exclusion criteria: Unwillingness to participate in study Patients who undergo systemic venous drainage Patients who undergo pancreas transplant alone (PTA)

Intervention groups

Both intervention and control groups include patients who are candidates SPK transplant in patients with type 1 diabetes. In intervention group, the extension of the right iliac artery is passed through the mesentery and placed next to the SMV for anastomosis. The Y graft is completely shortened and the carotid artery is removed from the donor for extension. In control group, a long Y graft is placed directly in the right iliac artery, while trying to reach the maximum length to maintain the anastomosis without stretching.

Main outcome variables

1. Operation time 2. Incidence of arterial complications 3. Incidence of postoperative pancreatitis 4. The cold ischemic phase 5. The warm ischemic time 6. Transplant rejection 7. Mortality

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210625051701N2**

Registration date: **2022-05-12, 1401/02/22**

Registration timing: **prospective**

Last update: **2022-05-12, 1401/02/22**

Update count: **0**

Registration date

2022-05-12, 1401/02/22

Registrant information

Name

Mohamad mahdi Mahmoudi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2246 5035

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-06-01, 1401/03/11

Expected recruitment end date

2023-06-01, 1402/03/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the outcomes and complications of use of extended carotid artery with Y-graft technique versus conventional Y-graft technique in pancreatic transplant surgery in the treatment of type 1 diabetic patients; A prospective randomized controlled trial

Public title

Evaluation of the results of two different pancreatic transplant surgery techniques in the treatment of type 1 diabetic patients

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patient's consent Pancreas transplant form (living donor or deceased donor) Having a simultaneous pancreas-kidney (SPK) transplant Patients with diabetic nephropathy who undergo portal venous drainage

Exclusion criteria:

Unwillingness to participate in study Patients who undergo systemic venous drainage Patients who undergo pancreas transplant alone (PTA)

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 60

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization is done by simple randomization method with individual units with the help of the help of Excel program randomization capability. In this method, for each of the numbers 1 to 60, one of letters of A (for the intervention group) and B (for the control group) are assigned equally. To execute a random sequence, the method of hiding numbered envelopes is used. In this method, the envelopes are numbered based on a random sequence, and inside the envelopes, the desired intervention, on which random allocation is written based on letter A or B, is provided to the executor with the condition that the envelopes are completely sealed, and the researcher, based on the order of patients' entry. Allocates them in the intervention group and the control group. The envelopes will be the same shape and will be prepared by an independent researcher. Patients are assigned to one of the two groups in order of enrollment

by number.

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**

Ethics committee of Shiraz University of Medical Sciences

Street address

Fars Province, Shiraz, Zand,

City

Shiraz

Province

Fars

Postal code

۷۱۳۴۸۱۴۳۳۶

Approval date

2022-04-18, 1401/01/29

Ethics committee reference number

IR.SUMS.MED.REC.1401.045

Health conditions studied**1****Description of health condition studied**

دیابت نوع 1

ICD-10 code

E10

ICD-10 code description

Type 1 diabetes mellitus

2**Description of health condition studied**

Pancreas transplant

ICD-10 code

Z94.83

ICD-10 code description

Pancreas transplant status

Primary outcomes**1****Description**

Transplant rejection

Timepoint

Up to 28 days after surgery
Method of measurement
Clinical features and diagnostic tests

2

Description
Incidence of arterial complications
Timepoint
Up to 28 days after surgery
Method of measurement
Sonography

3

Description
Mortality
Timepoint
Up to 28 days after surgery
Method of measurement
Absence of pulse rate and flat ECG

Secondary outcomes

1

Description
Operation time
Timepoint
During operation
Method of measurement
Using the timer

2

Description
Incidence of postoperative pancreatitis
Timepoint
Up to 28 days after surgery
Method of measurement
Lab data and Sonography

3

Description
The cold ischemic phase
Timepoint
From 24 hours before surgery
Method of measurement
Using the timer

4

Description
The warm ischemic time
Timepoint
From the time the donor organ is removed from the storage ice to the start of re-perfusion after transplantation
Method of measurement
Using the timer

Intervention groups

1

Description
Intervention group: Laparotomy will be performed first and then portal vein drainage will be done. In case of difficulty in exploration and exposing SMV, anastomosis to IVC will be performed. The right iliac artery is selected as the inflow and the anastomosis with the ileum will be done for GI drainage. Therefore, after exploring and finding the SMV, in the first group, an extension of the right iliac artery will be placed first. It will be passed through the mesentery and be placed next to the SMV for anastomosis. The Y-graft is completely shortened and the carotid artery will be harvested from the donor for extension.

Category
Treatment - Surgery

2

Description
Control group: Operation will be same as first group but in the second group, a long Y-graft will be inserted directly into the right iliac artery, while also trying to maintain the maximum length to reach the anastomosis without tension.

Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Abu Ali Sina Hospital
Full name of responsible person
Hamed Nikoupour Deilami
Street address
Fars Province, Sadra, Sadra Highway
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Hamed Nikoupour Deilami

Street address

Shiraz, Zand St., in front of Palestine St., the central building of Shiraz University of Medical Sciences

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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

Shiraz 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**

Shiraz University of Medical Sciences

Full name of responsible person

Mohamad mahdi Mahmoudi

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

General Surgery

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Full name of responsible person

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Subspecialist

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Person responsible for updating data**Contact****Name of organization / entity**

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Position

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Other areas of specialty/work

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

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

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

Undecided - It is not yet known if there will be 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

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