

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Jun 2026

Evaluation of Ascorbic Acid administration effect on gene expression level of IL6 and TNF- α cytokines among brain-dead liver donors

Protocol summary

Summary

The aim of this research is studying the effect of Ascorbic Acid administration on the expression of related inflammatory cytokine genes, so that we can present a solution to reduce organ injury and improve graft consequences after intensification of inflammatory responses in brain-dead liver donors. 10 up to 60 year-old brain-dead liver donors who are admitted in Namazi hospital and receive intensive care in ICU will be randomly classified into 2 groups: intervention and control. The intervention group cases receive only Ascorbic Acid with primary doze of 100 mg/kg, 6 hours before operation and immediately it will be continued with Ascorbic Acid infusion with doze of 100 mg/kg (per 6h) until the end of surgery and organ removal. The members of control group receive only routine care of ICU. The blood sample will be taken from every case at 3 times: - 6 hours before starting of donor operation (in intervention group before Ascorbic Acid administration) - Immediately after laparotomy - Immediately before Aorta clamping. At the end, expression level of related genes and function of transplanted liver will be compared in two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012081710619N1**

Registration date: **2013-02-25, 1391/12/07**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-02-25, 1391/12/07

Registrant information

Name

Masoumeh Kazemi

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Research Vice- Chancellor of Shiraz University of Medical Science

Expected recruitment start date

2012-04-20, 1391/02/01

Expected recruitment end date

2013-03-19, 1391/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of Ascorbic Acid administration effect on gene expression level of IL6 and TNF- α cytokines among brain-dead liver donors

Public title

The effect of Ascorbic Acid administration on inflammatory responses

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 10-60 y/o confirmed deadbrain case who has the UNOS standard criteria Exclusion criteria: The deadbrain patient who had a cardiac arrest

Age

From **10 years** old to **60 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

Other

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

Zand St, Shiraz University of Medical Sciences

City

Shiraz

Postal code

71348-14336

Approval date

2012-07-26, 1391/05/05

Ethics committee reference number

CT-91-6173

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

Exacerbation of inflammatory responses following brain-death occurrence

ICD-10 code

R00-R99

ICD-10 code description

Symptoms, signs and abnormal clinical and laboratory findings, not elsewhere classified

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

Gene expression levels of IL6 and TNF-a genes

Timepoint

- 6 hours before the operation of deadbrain donor (in intervention group before starting to intervention) - Immediately after laparotomy -Immediately before clamping of Aorta

Method of measurement

Gene expression analysis using Real-Time PCR method

Secondary outcomes**1****Description**

Serum levels of AST, ALT and Bilirubin -T

Timepoint

1, 3 and 10 days afetr liver transplantation

Method of measurement

Serum levels of AST, ALT and Bilirubin-T

Intervention groups**1****Description**

Intervention Group: 100 mg/kg Ascorbic Acid administration and then starting to Continuous infusion of vit C, 100 mg/kg/p6h until the end of donor operation
Control Group: without intervention

Category

Treatment - Drugs

2**Description**

Control group: routine practice

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Namazi hospital

Full name of responsible person

Dr Mohammad Bagher Khosarvi

Street address

Namazi hospital, Zand St

City

Shiraz

Sponsors / Funding sources**1****Sponsor**

Name of organization / entity

Vice chancellor for research, Shiraz University of
Medical Sciences

Full name of responsible person

Dr Gholamreza Hatam

Street address

Zand st, Shiraz University of Medical Sciences

City

Shiraz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research, Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Masoumeh Kazemi

Position

MSc Student of Human Genetics

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

Dr Mohammad Bagher Tabei

Position

Associated professor

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Person responsible for updating data

Contact

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Masoumeh Kazemi

Position

MSc student of Human Genetics

Other areas of specialty/work

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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