

# 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- $\alpha$ 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)

##### Phone

+98 71 1234 9610

##### Email address

kazemima@sums.ac.ir

##### 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- $\alpha$  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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Medical Genetics Department, Medical Faculty, Setad  
Square

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## Person responsible for scientific inquiries

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Dr Mohammad Bagher Tabei

**Position**

Associated professor

**Other areas of specialty/work**

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MSc student of Human Genetics

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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*