

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Effect of receiving intravenous vitamin c on fatigue in patients undergoing hemodialysis in baqiatallah hospital Tehran 1391

#### Protocol summary

2013-02-17, 1391/11/29

#### Summary

**Aims:** Fatigue is one of the most common dialysis side effects and nursing diagnoses in hemodialysis patients. It can as a Bioalarm predict cardiovascular events and mortality in hemodialysis patients. The aim of this study is evaluate the effect of vitamin C supplementation on fatigue in hemodialysis patients. **Methods:** In a randomized, double-blind clinical trial, 177 patients with chronic renal failure who were referred to Baqiatallah and Chamran hospitals in Tehran, Iran were studied. They were distributed in three groups (case: one group and control: two groups). Inclusion criteria including regular hemodialysis at least 12 weeks; lack malignant and active blood disease; lack history of major surgery in the last 6 months; do not use of Carnitine; no smoking and no use of oral and injectable forms of vitamin C. Exclusion criteria including: refusal to continue the study and recent hemorrhage history and malignant disease. In addition to demographic questionnaire, used multidimensional questionnaire (MFI), that it is determining the fatigue. Then injected Amp Vitamin C 250 mg three times weekly at the end of each dialysis session via the intravenous route, for 8 weeks in case group. In the first control group injected the same amount and at the same time of placebo and the third group received nothing.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201212212046N2**  
Registration date: **2013-02-17, 1391/11/29**  
Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

#### Registrant information

##### Name

Mehdi Sadeghi Shermeh

##### Name of organization / entity

Nursing Faculty, Baqiyatallah University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

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##### Email address

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#### Recruitment status

##### Recruitment complete

#### Funding source

Nephrology Research Center of the Baqiyatallah University of Medical Sciences Nursing school of Baqiyatallah university of Medical Sciences

#### Expected recruitment start date

2012-08-15, 1391/05/25

#### Expected recruitment end date

2012-12-21, 1391/10/01

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Effect of receiving intravenous vitamin c on fatigue in patients undergoing hemodialysis in baqiatallah hospital Tehran 1391

#### Public title

Effect of receiving intravenous vitamin c on fatigue in patients undergoing hemodialysis in baqiatallah hospital Tehran 1391

## Purpose

Treatment

## Inclusion/Exclusion criteria

Inclusion criteria: patients with continuous and regular hemodialysis with age from 18 to 80 years of hearing ability, speech, and consciousness acceptable answer to the question of taking the form of oral or intravenous vitamin c Exclusion criteria: appearance of adverse drug unwillingness to continue the study

## Age

From **18 years** old to **90 years** old

## Gender

Both

## Phase

N/A

## Groups that have been masked

*No information*

## Sample size

Target sample size: **190**

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Double blinded

## Blinding description

## Placebo

Used

## Assignment

Parallel

## Other design features

The study groups consisted of three treatment , placebo and control groups

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Baqiyatallah university of Medical Sciences

##### Street address

Tehran

##### City

Tehran

##### Postal code

#### Approval date

2012-04-16, 1391/01/28

#### Ethics committee reference number

30

## Health conditions studied

### 1

#### Description of health condition studied

End stage renal disease

#### ICD-10 code

N18

#### ICD-10 code description

Chronic kidney disease

## Primary outcomes

### 1

#### Description

Fatigue

#### Timepoint

Before and after intervention

#### Method of measurement

MFI: Standard questionnaire for fatigue measurement

### 2

#### Description

Marital Satisfaction

#### Timepoint

Before and after intervention

#### Method of measurement

ENRICH Couple Scales: standard questionnaire for Marital Satisfaction measurement

## Secondary outcomes

### 1

#### Description

Hb and Hct

#### Timepoint

Before intervention, one month and after the end of intervention

#### Method of measurement

CBC laboratory Test

## Intervention groups

### 1

#### Description

In the Case group: Amp Vitamin C 250 mg injected three times in the everyweek at the end of each dialysis session via the intravenous route, for 8 weeks.

#### Category

Treatment - Drugs

### 2

#### Description

In the control group: Amp Normal saline 2.5 cc(placebo saline) injected in the everyweek at the end of each dialysis session via the intravenous route, for 8 weeks.

#### Category

Placebo

### 3

#### Description

In the witness group: performed no intervention

#### Category

N/A

## Recruitment centers

### 1

#### Recruitment center

**Name of recruitment center**

Baqiyatallah hospitals

**Full name of responsible person**

Mr Jalilzade- Ms Dini

**Street address****City**

Tehran

### 2

#### Recruitment center

**Name of recruitment center**

Shahid Chamran hospital

**Full name of responsible person**

Mr Seif

**Street address****City**

Tehran

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Nephrology Research Center of Baqiyatallah university of Medical Sciences

**Full name of responsible person**

Dr Einollahi

**Street address**

Tehran - Vanak Square - Mulla Sadra Street - The intersection of Sheikh Bahai - Alley martyr Nosrati

**City**

Tehran

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Nephrology Research Center of Baqiyatallah university of Medical Sciences

**Proportion provided by this source****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*

### 2

#### Sponsor

**Name of organization / entity**

School of Nursing of Baqiyatallah university of Medical Sciences

**Full name of responsible person**

Dr Ebadi

**Street address**

Tehran- Noboyad square- Araj Tee- School of Nursing of Baqiyatallah university of Medical Sciences

**City**

Tehran

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

School of Nursing of Baqiyatallah university of Medical Sciences

**Proportion provided by this source****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**

School of Nursing Baqiyatallah University of Medical Sciences

**Full name of responsible person**

Mahdi Sadeghi Shermeh

**Position**

Baqiyatallah university 's Faculty member

**Other areas of specialty/work****Street address**

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## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**

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**Full name of responsible person**

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**Position**

PhD student Nursing

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

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**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*