

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

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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

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

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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

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Person responsible for scientific inquiries

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Full name of responsible person

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Position

PhD student Nursing

Other areas of specialty/work

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Person responsible for updating data

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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