

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The effect of vitamin B12 supplementation on levels of fatigue, depression, anxiety and stress hemodialysis patients

Protocol summary

Summary

The aim of this study was to determine the effect of vitamin B12 supplementation on fatigue, depression, anxiety and stress in hemodialysis patients. High plasma concentrations of total homocysteine was considered as a criterion. Study was on hemodialysis patients from selected hospitals No.1 and No.2. The sample size was 86 patients involved intravenous injection of ml/mcg 100 Vitamin B12 after dialysis process, which was carried out three times a week for two months and then by the end of the intervention, to assess the durability of vitamin B12, there was no intervention for a month(washout). 21-item questionnaire measure of depression, anxiety, stress and multidimensional questionnaire measuring fatigue at the beginning and end of each month of study was completed by participants. At the beginning of Intervention, at the end of the second month of intervention and end of washout, laboratory studies were conducted.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012122611892N1**

Registration date: **2013-01-28, 1391/11/09**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2013-01-28, 1391/11/09

Registrant information

Name

Samira Savari

Name of organization / entity

Faculty of Nursing of Baqiyatallah University of

Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 7710 3725

Email address

rnehrr1739@bmsu.ac.ir

Recruitment status

Recruitment complete

Funding source

Nephrology and Urology Research center Faculty of Nursing of Baqiyatallah University of Medical Science.
Responsible person: Dr Behzad Eynollahi

Expected recruitment start date

2011-12-21, 1390/09/30

Expected recruitment end date

2012-03-19, 1390/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of vitamin B12 supplementation on levels of fatigue, depression, anxiety and stress hemodialysis patients

Public title

Effect of vitamin B12 on reducing fatigue, depression, anxiety and stress in hemodialysis patients

Purpose

Supportive

Inclusion/Exclusion criteria

inclusion criteria: a minimum of 18 years; a minimum literacy; a least 3 months have passed since the first dose of hemodialysis; a high concentration of plasma total homocysteine exclusion criteria: people who did research during strenuous crisis(acute illness,

hospitalization, surgery extended) or emotional (grief, divorce)they are excluded

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **86**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Baqiyatallah University of Medical Sciences

Street address

Molla sadra Ave,Vanak

City

Tehran

Postal code

Approval date

2011-11-29, 1390/09/08

Ethics committee reference number

28

Health conditions studied

1

Description of health condition studied

hemodialysis

ICD-10 code

Z49.0

ICD-10 code description

Preparatory care for dialysis

Primary outcomes

1

Description

Fatigue

Timepoint

Befor Intervention, one and two months after intervention, One month after the end of intervention

Method of measurement

MFI

Secondary outcomes

1

Description

Total homocysteine plasma

Timepoint

Befor intervention, two months after the intervention, one month after the end of intervention

Method of measurement

laboratory tests

Intervention groups

1

Description

Infusion intravenous vitamin B12 two months in the end of hemodialysis procccece

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Baqiatallah, Chamran Hospitals

Full name of responsible person

Samira Savari

Street address

Room 408, Fourth Floor, Block 16, Provincial Park, Martyr Babaei Highway

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Nephrology and Urology Research center Baqiyatallah University of Medical Sciences

Full name of responsible person

Dr. Behzad Eynollahi

Street address

Molla Sadra Ave, Vanak

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor

organization/entity?

Yes

Title of funding source

Nephrology and Urology Research center Baqiyatallah 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**

Faculty of Nursing of Baqiyatallah University of Medical Sciences

Full name of responsible person

Samira Savari

Position

MSc

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

Room 408, Fourth Floor, Block 16, Provincial Park, Martyr Babaei Highway

City

Tehran

Postal code**Phone**

+98 21 7710 3725

Fax**Email**

Savari.samira@yahoo.com

Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Faculty of Nursing of Baqiyatallah University of Medical Sciences

Full name of responsible person

Ali Tayyebi

Position

Master of Nursing Education

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

Faculty of Nursing of Baqiyatallah University of Medical Sciences

City

Tehran

Postal code**Phone**

+98 21 2228 9941

Fax**Email**

TAYYBI ALI@GMAIL.COM

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

Faculty of Nursing of Baqiyatallah University of Medical Sciences

Full name of responsible person

Samira Savari

Position

MSc

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

Room 408, Fourth Floor, Block 16, Provincial Park, Martyr Babaei Highway

City

Tehran

Postal code**Phone**

+98 21 7710 3725

Fax**Email**

Savari.samira@yahoo.com

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