

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jul 2026

The effect of care plan based on the model of consistency "Roy" on physiological parameters in patients with chronic renal failure

Protocol summary

Summary

Objectives: The aim of this study is to determine the effect of care plan based on the "Roy" adaptation model on the physiological parameters of chronic renal failure patients. Design: This study is a randomized clinical intervention. Methods: This study involved two group of 60 patients with chronic renal failure. Each group consist of 30 patients. Random allocation of samples will be done using block randomization. Intervention: An educational period of over two months on the physiological parameters such as nutrition, rest and activity will be done. Before and after intervention "Roy" questionnaire will be used to assess the effect of education. Inclusion criteria: Inclusion criteria included patients with complete consciousness, having six-months history of chronic renal disease, age older than 18 years and less than 60 years. Exclusion criteria: Exclusion criteria included lack of desire to continue cooperation, transfer to the others.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016042627604N1**

Registration date: **2016-08-24, 1395/06/03**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-08-24, 1395/06/03

Registrant information

Name

Mandana Madani

Name of organization / entity

Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 81 3822 6580

Email address

barzou@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor of Hamadan University of Medical Sciences

Expected recruitment start date

2016-02-20, 1394/12/01

Expected recruitment end date

2016-05-21, 1395/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of care plan based on the model of consistency "Roy" on physiological parameters in patients with chronic renal failure

Public title

Nursing care in chronic kidney disease

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: complete consciousness; Having six-months history of chronic renal failure; Age over 18 years and less than 60 years. Exclusion criteria: Lack of patient cooperation during study; Transfer to another center.

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size:

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Hamadan University of Medical Sciences

Street address

Fahmide Street-Hamadan University of Medical Sciences-Hamadan

City

Hamadan

Postal code

Approval date

2016-01-23, 1394/11/03

Ethics committee reference number

IR.UMSHA.REC.1394.459

Health conditions studied

1

Description of health condition studied

kidney disease

ICD-10 code

N-18

ICD-10 code description

Chronic kidney disease

Primary outcomes

1

Description

Vomiting

Timepoint

Before and 2 months after intervention

Method of measurement

Roy questionnaire

Secondary outcomes

1

Description

Rest

Timepoint

Before and 2 months after intervention

Method of measurement

Roy questionnaire

Intervention groups

1

Description

Interventions 1: In the intervention group educational program in eight sessions in relation to physiological parameters such as nutrition, resting and activities for patients will be done during two months.

Category

Prevention

2

Description

Intervention 2: Will not be given any training in control group.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Beheshti Hospital

Full name of responsible person

Mandana Madany

Street address

Fahmide Street-Hamadan University of Medical Sciences-Hamadan

City

Hamadan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor of Hamadan University of Medical Sciences

Full name of responsible person

Mandana Madani

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Fahmide Street-Hamadan University of Medical Sciences-Hamadan

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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice Chancellor of Hamadan 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
Hamadan University of Medical sciences
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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