

# 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

##### Street address

Fahmide Street-Hamadan University of Medical Sciences-Hamadan

##### City

Hamedan

**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  
**Full name of responsible person**  
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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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*