

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparison the effect of individual care with routine care on the treatment adherence among hemodialysis patients

Protocol summary

Summary

The purpose of this study was the comparison of the effect of individual multistages care with routine care on the treatment adherence among hemodialysis patients. This study was an experimental study with simple random allocation. The study population was consisted of hemodialysis patients at Hajar hospital in Shahrekord. Fifty-six patients were divided randomly in two intervention and control groups (each group 28 patients). Inclusion criteria were age higher than 18 years old, having reading and writing ability, to get dialysis treatment 3 times a week, and non-adherence to fluid and diet limitation according to treatment adherence questionnaire and laboratory findings. Exclusion criteria were background diseases such as cancer and lupus. The Patients in control group received routine care. The patients in intervention group participated in eight individual care intervention sessions (each session 1 hour) in addition to routine care. At the first and the end of the study, treatment adherence questionnaire was completed for patients in two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012091710857N1**

Registration date: **2013-07-15, 1392/04/24**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2013-07-15, 1392/04/24

Registrant information

Name

Leila Rafiee Vardanjani

Name of organization / entity

Golestan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 17 1442 6900

Email address

rafiee_l@studentgoums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research and technology, Golestan University of Medical Sciences, Gorgan, Iran

Expected recruitment start date

2013-03-19, 1391/12/29

Expected recruitment end date

2013-05-22, 1392/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effect of individual care with routine care on the treatment adherence among hemodialysis patients

Public title

Comparison the effect of individual care with routine care on the treatment adherence among hemodialysis patients

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Age higher than 18 years old, having reading and writing ability, to get dialysis treatment 3 times per week, and non-adherence to fluid and diet limitation according to treatment adherence

questionnaire and laboratory findings. Exclusion criteria:
Background diseases such as cancer and lupus.

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **56**

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 Golestan University of Medical Sciences

Street address

Kilometer 4 Gorgan-Sari Road, Initial of Shast Kolah Road, Golestan University of Medical Sciences, Gorgan

City

Gorgan

Postal code

Approval date

2013-03-17, 1391/12/27

Ethics committee reference number

356191122721

Health conditions studied

1

Description of health condition studied

Chronic kidney disease, stage 5

ICD-10 code

N18.5

ICD-10 code description

End stage kidney disease

Primary outcomes

1

Description

Treatment adherence

Timepoint

At the first and the end of the study

Method of measurement

Treatment adherence questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Control group: Patients in control group received routine care.

Category

Behavior

2

Description

Intervention group: Patients in the intervention group participated in eight personal intervention sessions in addition to routine care when they were under hemodialysis. The intervention was done by the researcher in step-by-step process with the aim of change in patient's behaviors.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Hajar hospital

Full name of responsible person

Leila Rafiee Vardanjani

Street address

Hajar hospital, Parastar Street, Shahrekord

City

Shahrekord

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research and technology, Golestan University of Medical Sciences

Full name of responsible person

Mohammad Jafar Golalipour

Street address

Kilometer 4 Gorgan-Sari Road, Initial of Shast Kolah
Road, Golestan University of Medical Sciences,
Gorgan

City

Gorgan

Grant name

Grant code / Reference number

**Is the source of funding the same sponsor
organization/entity?**

Yes

Title of funding source

Vice chancellor for research and technology, Golestan
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

Golestan University of Medical Sciences

Full name of responsible person

Leila Rafiee Vardanjani

Position

MSc Nursing Student

Other areas of specialty/work

Street address

Kilometer 4 Gorgan-Sari Road, Initial of Shast Kolah
Road, Golestan University of Medical Sciences,
Gorgan

City

Gorgan

Postal code

Phone

+98 17 1442 6900

Fax

Email

rafiee.leila@yahoo.com

Web page address

**Person responsible for scientific
inquiries**

Contact

Name of organization / entity

Golestan University of Medical Sciences

Full name of responsible person

Gholamreza Mahmoodi Shan

Position

PhD, Assistant Professor

Other areas of specialty/work

Street address

Kilometer 4 Gorgan-Sari Road, Initial of Shast Kolah
Road, Golestan University of Medical Sciences,
Gorgan

City

Gorgan

Postal code

Phone

+98 17 1442 6900

Fax

+98 17 1442 5171

Email

mahmoodigh@yahoo.com

Web page address

www.Goums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Golestan University of Medical Sciences

Full name of responsible person

Leila Rafiee Vardanjani

Position

MSc Nursing Student

Other areas of specialty/work

Street address

Kilometer 4 Gorgan-Sari Road, Initial of Shast Kolah
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Gorgan

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Gorgan

Postal code

Phone

+98 17 1442 6900

Fax

Email

rafiee.leila@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