

The role of clinical pharmacists' intervention on improving the adherence to treatment and clinical outcomes among hemodialysis patients

Submission date 23/03/2022	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 25/03/2022	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 14/07/2022	Condition category Urological and Genital Diseases	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Hemodialysis is a procedure where a dialysis machine and a special filter called an artificial kidney, or a dialyzer, are used to clean your blood.

Following treatment recommendations (adherence) is challenging in hemodialysis (HD) patients, yet it has been found to be extremely crucial in obtaining positive clinical and health outcomes.

This study aimed to evaluate the role of clinical pharmacists in enhancing HD patients' adherence to treatment recommendations and improving clinical outcomes.

Who can participate?

Adult (over 18 years) hemodialysis patients who have been undergoing dialysis for more than three months

What does the study involve?

Patients will receive a monthly educational session, for three months, that covers the disease and its management with recommendations for improving adherence and quality of life. An instructional booklet will be handed to participants in the intervention group as well.

What are the possible benefits and risks of participating?

This study will be beneficial to participants in improving management outcomes. No minimal risk is expected.

Where is the study run from?

Jordan University of Science and Technology

When is the study starting and how long is it expected to run for?

March 2021 to November 2021

Who is funding the study?

This work was supported by the Deanship of Scientific Research at Jordan University of Science and Technology (grant number 232/2021).

Who is the main contact?

Dr Osama Alshogran, oyalshogran@just.edu.jo

Contact information

Type(s)

Principal Investigator

Contact name

Dr Osama Alshogran

ORCID ID

<http://orcid.org/0000-0002-2466-4763>

Contact details

Faculty of Pharmacy/Jordan University of Science and Technology

Irbid

Jordan

22110

+962 798318927

oyalshogran@just.edu.jo

Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

Grant number 232/2021

Study information

Scientific Title

The role of clinical pharmacist in enhancing hemodialysis patients' adherence and clinical outcomes: a randomized-controlled study

Study objectives

The intervention group, which received education from a clinical pharmacist, would be more committed to the recommendations, have fewer complications, and improved clinical outcomes, as compared to the control group (who received standard medical care provided by other health care providers).

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 26/04/2021, Institutional review board (IRB) committee at Jordan University of Science and Technology (King Abdullah University 7th Floor - Wing D., Amman - Ramtha highway Irbid Jordan; +962 2 7200600 Ext. (45102); IRB@just.edu.jo), ref: 11/140/2021

Study design

Randomized open-label clinical trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Quality of life

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet.

Health condition(s) or problem(s) studied

Adherence to treatment in dialysis patients

Interventions

Using stratified sampling based on age and gender, eligible patients were randomly assigned to intervention or control groups.

The intervention group will receive an educational instructional session by a clinical pharmacist that covers recommendations about the disease and its complications, medication information and adherence, common adverse drug events and how to prevent them, the value of adherence to diet and fluid restrictions, the importance of regular follow-up with the medical team and undertaking required laboratory testing, and doing exercise.

The control will receive the usual care.

Follow up is for 3 months.

Intervention Type

Behavioural

Primary outcome measure

Overall adherence to treatment recommendations assessed using a previously validated ESRD-AQ tool. This was assessed at baseline and after three months of follow up

Secondary outcome measures

1. Quality of life measured using KDQOLTM-36 at baseline and after three months of follow up
2. Disease awareness measured using interview with clinical pharmacist at baseline and after three months of follow up
3. Number of emergency or hospital admissions measured using patient records for three

months of follow up

4. Biochemical measurements included serum levels of sodium, potassium, urea, creatinine, albumin, hemoglobin level, calcium, phosphorus, and PTH which were obtained from patients' medical records at baseline and after three months of follow up

Overall study start date

31/03/2021

Completion date

30/11/2021

Eligibility

Key inclusion criteria

1. At least 18 years old
2. Been on continuous HD for at least three months
3. Stable medical condition

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

120

Total final enrolment

114

Key exclusion criteria

1. Mental disease
2. Malignancies
3. Acute illness
4. Terminally ill
5. Under irregular dialysis

Date of first enrolment

01/05/2021

Date of final enrolment

01/09/2021

Locations

Countries of recruitment

Jordan

Study participating centre

King Abdullah University Hospital

Irbid

Jordan

22110

Study participating centre

Al-Rashid Hospital

Amman

Jordan

11937

Study participating centre

Al-Essra Hospital

Amman

Jordan

11941

Sponsor information**Organisation**

Jordan University of Science and Technology

Sponsor details

Deanship of research

Irbid

Jordan

22110

+962 27201000

research@just.edu.jo

Sponsor type

University/education

Website

<https://www.just.edu.jo/Deanships/DeanshipofResearch/Pages/Default.aspx#>

ROR

Funder(s)

Funder type

University/education

Funder Name

Deanship of Research, Jordan University of Science and Technology

Alternative Name(s)

Funding Body Type

Government organisation

Funding Body Subtype

Universities (academic only)

Location

Jordan

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal

Intention to publish date

01/04/2022

Individual participant data (IPD) sharing plan

The datasets generated during and/or analyzed during the current study are/will be available upon reasonable request from authors
oyalshogran@just.edu.jo

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		12/07/2022	14/07/2022	Yes	No