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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

Registration date
25/03/2022

Overall study status
Completed

Last Edited
14/07/2022

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

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Additional identifiers

Protocol serial number
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

Primary study design
Interventional

Study design
Randomized open-label clinical trial

Study type(s)
Quality of life

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(s)
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

Key secondary outcome(s)
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

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

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

ROR
https://ror.org/03y8mtb59

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

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