ISRCTN13609931 https://doi.org/10.1186/ISRCTN13609931

Exploring the determinants of dialysis adequacy in maintenance hemodialysis patients, with a focus on modifiable risk factors and clinical intervention measures

Submission date
25/02/2025

Recruitment status
No longer recruiting

Registration date
27/02/2025

Overall study status
Completed

Last Edited
10/07/2025

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
Dialysis adequacy is a pivotal factor in maintaining the health and quality of life of patients undergoing maintenance hemodialysis (MHD). It is essential to assess the current status of dialysis adequacy and identify the factors that influence it to optimize treatment outcomes. The primary objective of this study is to evaluate the status of dialysis adequacy in MHD patients. Additionally, the study aims to analyze and identify the modifiable risk factors and clinical interventions that significantly affect dialysis adequacy.

Who can participate?
Patients who are currently undergoing MHD at a participating hemodialysis center

What does the study involve?
The participants are categorized based on their dialysis adequacy as assessed by the single pool Kt/V (spKt/V) method. This cross-sectional study involves collecting data on demographics, hemodialysis parameters, and laboratory indicators from the participating MHD patients. Dialysis adequacy is then evaluated using the spKt/V method. Patients are grouped into adequate (spKt/V ≥ 1.2) and inadequate (spKt/V < 1.2) dialysis categories. Statistical analyses are performed to identify significant factors associated with dialysis adequacy.

What are the possible benefits and risks of participating?
Benefits: The study may contribute to improving the understanding of factors that affect dialysis adequacy, which can lead to better treatment strategies and improved outcomes for MHD patients.
Risks: There are minimal risks associated with participating in this study, as it primarily involves the collection of existing medical data and routine laboratory tests. However, there may be some discomfort or inconvenience associated with the data collection process.

Where is the study run from?
The hemodialysis center of the China-Japan Friendship Hospital in Beijing, China

When is the study starting and how long is it expected to run for?
November 2023 to November 2024

Who is funding the study?
China-Japan Friendship Hospital, China

Who is the main contact?
Dr Jia Wanning, 446781575@qq.com

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Dr Jia Wanning

ORCID ID
https://orcid.org/0000-0002-8366-814X

Contact details
Blood Purification Center, China-Japan Friendship Hospital, No. 2, East Yingsha Street, Chaoyang District
Beijing
China
100029
-
446781575@qq.com

Additional identifiers

Study information

Scientific Title
Determinants of dialysis adequacy in maintenance hemodialysis patients: a cross-sectional study on modifiable risk factors and clinical interventions

Study objectives
Maintenance hemodialysis (MHD) is a critical renal replacement therapy for patients with end-stage renal disease (ESRD), aimed at prolonging survival, reducing mortality, and enhancing the quality of life. The adequacy of dialysis plays an essential role in achieving these outcomes. Research indicates that nearly 60% of MHD patients fail to attain adequate dialysis treatment. Currently, the single pool Kt/V (spKt/V) model is commonly employed to assess dialysis adequacy in MHD patients. The Kidney Disease Outcomes Quality Initiative (K/DOQI) recommends a target spKt/V value of 1.4, with a minimum measured value of 1.2. Notably, when spKt/V falls below 1.2, there is a significant increase in patient mortality rates. However, dialysis adequacy can be influenced by various factors, including individual patient characteristics,

dialysis treatment technologies, and dialyzers. Therefore, for patients exhibiting inadequate spKt /V levels, medical staff need to conduct a thorough analysis of the specific causes underlying the insufficient dialysis to adjust subsequent treatment plans accordingly.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 06/11/2023, Clinical Research Ethics Committee of the China-Japan Friendship Hospital (No. 2, East Yingsha Street, Chaoyang District, Beijing, 100029, China; +86 (0)10-84206250; zryyec@126.com), ref: 2023-KY-300-1

Primary study design
Observational

Study design
Retrospective cross-sectional single-centre study

Study type(s)
Diagnostic, Prevention, Treatment

Health condition(s) or problem(s) studied
Influencing factors of dialysis adequacy in hemodialysis patients

Interventions
Data on demographics, hemodialysis parameters, and laboratory indicators were collected. Dialysis adequacy was assessed using the single pool Kt/V (spKt/V) method. Patients were categorized into adequate (spKt/V ≥ 1.2) and inadequate (spKt/V < 1.2) dialysis groups.

Intervention Type
Not Specified

Primary outcome(s)
The adequacy of small molecule removal measure using the single-pool Kt/V value during a single session

Key secondary outcome(s)
1. General data such as gender, age and living conditions were measured at the time of patient enrollment
2. Dialysis duration, dry weight, ultrafiltration volume, vascular access and oxygen inhalation status were recorded and measured based on the doctor's orders at the time of patient enrollment
3. Laboratory test indicators were recorded based on the last test result at the time of patient enrollment
4. spKt/V was recorded based on the last test result at the time of patient enrollment

Completion date
18/11/2024

Eligibility

Key inclusion criteria
1. Patients were diagnosed with ESRD and receiving MHD treatment
2. Hemodialysis 3 times a week, each treatment time is 4 hours and lasts for more than 3 months
3. Age ≥18 years old
4. The ability of hearing and language expression is normal and can cooperate with the investigation
5. Informed consent to participate in this study

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Total final enrolment
232

Key exclusion criteria
1. Combined with other infectious diseases, malignant tumors or serious organic diseases of other organs
2. Complicated with mental diseases, unable to complete the study

Date of first enrolment
01/06/2024

Date of final enrolment
31/10/2024

Locations

Countries of recruitment
China

Study participating centre
China- Japan Friendship Hospital
Blood Purification Center
No. 2, East Yingsha Street
Chaoyang District
Beijing

China
100029

Sponsor information

Organisation
China-Japan Friendship Hospital

ROR
https://ror.org/037cjxp13

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
China-Japan Friendship Hospital

Alternative Name(s)
CJFH

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
China

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Dr Jia Wanning, 446781575@qq.com

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?

Results article	09/07/2025	10/07/2025	Yes	No