

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

<b>Submission date</b> 25/02/2025	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 27/02/2025	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 10/07/2025	<b>Condition category</b> Urological and Genital Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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 ( $\text{spKt/V} \geq 1.2$ ) and inadequate ( $\text{spKt/V} < 1.2$ ) 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

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## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

### ClinicalTrials.gov (NCT)

Nil known

### Protocol serial number

Nil known

## 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

### **Study design**

Retrospective cross-sectional single-centre study

### **Primary study design**

Observational

### **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 ( $\text{spKt/V} \geq 1.2$ ) and inadequate ( $\text{spKt/V} < 1.2$ ) 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  $\geq 18$  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?
<a href="#">Results article</a>		09/07/2025	10/07/2025	Yes	No