STUDY INFORMATION AND INFORMED CONSENT FORM

There are [4] parts to this document:

Part I: the "**Study Information**" essential to your decision to take part in the clinical study.

Part II: the "**Future Research Information**" which explains the possibility to contribute to future research.

Part III: your "**Consent Form**" which summarise what you may agree to.

Part IV: supplementary information in the "***Additional information for patients***" Section.

PART I: STUDY INFORMATION

[Study number D9480R00033]

Title of study: Hyperkalaemia Prevalence, Recurrence and Treatment in Haemodialysis: A prospective multi-centre cohort study

Dear Madam/Sir,

You are invited to take part in this study because you are diagnosed with end stage renal disease (ESRD) and is on haemodialysis (HD). Participation requires your written consent. Before you decide whether you want to participate in this study, you will be given an explanation about what the study involves.

The overall description of this study has been reviewed by an independent Ethics Committee to ensure that the rights, safety and well-being of study patients are protected.

Your condition may not improve if you join the study. But, the information we get from this study might help other patients with the same condition in the future.

1 What is this study about?

We are doing this study to learn more about occurrence and recurrence of hyperkalaemia（HK） in Chinese HD patients and to understand the treatment pattern of HK in China and also to better understand the risk factors associated with HK.

About 600 people from approximate 15 hospitals will take part in this study.

2 Do I have to take part?

You have a choice whether or not you would like to participate.

Please take as much time as you need to make a decision about whether or not you would like to participate in this study. It may be helpful to talk with your friends and family as you make this decision.

If you join the study, you can leave at any time (see “section 10” for more details). Leaving will not affect your care. If you choose to leave the study, please let your study doctor know as soon as possible.

If you don’t join the study, you will continue to receive care for your disease. Your study doctor or treating physician will talk to you about other possible treatments, their risks and benefits.

3 What will happen if I join the study?

Because this is an observational study, no medications or other treatments are provided to you by the Sponsor as part of this study.

You will continue to come for your routine doctor’s appointments and to take your regular medication as prescribed by your doctor.

You will be in the study for about 6 months.

During the visits, information will be collected for the study and this might add some extra time to your routine visit of approximately 10 minutes.

If you cannot come to a visit, you must tell your study doctor.

Please note that the study, and your participation in the study, may be stopped earlier than expected, for example for scientific or safety reasons (see “section 6” for more details).

4 What are the required tests and procedures?

To conduct the study, some tests and procedures will have to be performed on you.

In addition to the standard of care examinations for the disease the following tests and procedures will be included:

- **Enrolment(Day 1, 1 visit)**: You will be in Long interdialytic interval (LIDI) at enrolment.
  - ✓ Demographic characteristics
    - Your general information such as age, gender and race will be collected.
  - ✓ Medical history, Etiology of ESRD
    - Your study doctor will collect information about your medical history (history of previous disease and surgery history) and the cause of ESRD.
  - ✓ Clinical evaluations and laboratory tests
    - Clinical evaluations, which include vascular access, physical examination, height, pre-dialysis and post-dialysis weight, electrocardiography (ECG), echocardiography(not mandatory), blood pressure, pulse, heart rate will be performed.
    - You blood will also be tested for pre-dialysis and post-dialysis serum K+, pre-dialysis BUN and post-dialysis BUN, Blood routine, Biochemistry measurements, Blood gas analysis.
    - Dialysis prescription and frequency will be collected. Dialysis adequacy will be evaluated.
  - ✓ Concomitant medication
    - Any medication used by you while participating in this study will be collected for dosage, duration and mode of administration.
- **Follow-up(24 weeks, 7 or 8 visits)**: You will be in short interdialytic interval (SIDI) at visit 2 (if applicable) and in LIDI at visit 3-8.

  Visit 2(Only applicable for HD received thrice a week)
  - ✓ Clinical evaluations and laboratory tests
    - Clinical evaluations, which include physical examination, pre-dialysis and post-dialysis weight, blood pressure, pulse, heart rate will be performed.
    - You blood will also be tested for pre-dialysis serum K+.

- ✓ Concomitant medication
  - Any medication used by you while participating in this study will be collected for dosage, duration and mode of administration.

Visit 3-8

- ✓ Clinical evaluations and laboratory tests
  - Clinical evaluations, which include vascular access, physical examination, pre-dialysis and post-dialysis weight, electrocardiography (ECG, not mandatory), echocardiography(not mandatory), blood pressure, pulse, heart rate will be performed when you visit the study site according to the study schedule.
  - You blood will also be tested for pre-dialysis and post-dialysis serum K+(not mandatory), pre-dialysis BUN and post-dialysis BUN, Blood routine, Biochemistry measurements, Blood gas analysis when you visit the study site according to the study schedule.
  - Dialysis prescription and frequency will be collected, and dialysis adequacy(evaluated at V5) will be evaluated at each visit.
  - Urine 24- hour volume and biochemistry measurements will be performed at V3 or V4.
- ✓ Concomitant medication
  - Any medication used by you while participating in this study will be collected for dosage, duration and mode of administration at each visit.

The complete list of tests and procedures, including their detailed schedule is available in “part 4: Additional Information for Patients”.

5 What are the risks and possible benefits of joining the study?

There is no immediate clinical benefit for you, however the information we get from this study may help us to describe how HD patients with HK are managed in real-life practice, and to increase our knowledge about the disease and its symptoms. This will hopefully help us to better treat HD patients with HK in the future.

Since the study is observational, it will not change how your disease is managed by your doctor. There are no physical risks of taking part in this study.

6 What happens if something changes while I am in the study, e.g., if new information is found?

Changes may happen in the study that could make you change your mind about continuing to take part. If something changes, we will tell you as soon as possible.

You can choose to leave the study at any time. For more details see section 10 below.

The study doctor can also choose to take you out of the study if they believe that it is best for you.

Your participation in the study also stops when the Sponsor, health authorities, the ethics or regulatory agencies decide that the study must be stopped.

7 What happens if I am harmed or injured during the study?

If you become ill or are injured while you are in this study, you must tell your study doctor straight away.

Injuries that have been caused by the study tests or procedures are called 'research injuries'. Injuries caused by your usual medical care or your disease, are not research injuries.

The Sponsor has an insurance to cover the costs of research injuries as long as you have followed your study doctor´s instructions. Sponsor will pay the costs of medical treatment for research injuries, provided that the costs are reasonable, and you did not cause the injury yourself.

8 What will happen to my data gathered in the study?

a. Which data are collected?

In order to conduct the study, the Study site will have to collect and register information about your identity (such as your name, address, telephone number) as well as data that is necessary to assess your health conditions, your medical condition and medical history (this may include information from your physicians/ available in your medical records), your demographics (age, gender, *ethnic*).

b. What are my data needed for?

Your data are needed to better understand the studied disease and associated health problems and publish research results in scientific journals or use them for educational purposes.

c. Who can access my data?

Only at the study site, your name and contact details will be accessible to the study doctor and the study team to conduct the study. Non-medical personnel acting on behalf of the sponsor and being bound by a duty of confidentiality as well as Health authorities and Ethics Committees may also be given access to this data only to verify that the study is carried out in compliance with legal and quality requirements.

The study site will share your data with the sponsor but only after they have been coded (which means that your name, contact details have been replaced by a code). The sponsor may share your coded data with its Research partners and Service providers for the purposes of a drug development programme.

In order to ensure proper conduct and accurate results of the study the sponsor will share your coded data with authorities and possibly with Ethics Committees. They may also be shared with scientific journals, so the study results can be reviewed by independent scientists and to ensure the accuracy of results.

In **none** of these cases your identity will be revealed.

Some of the above-mentioned persons may be located outside your country. If this other country does not have equivalent personal data protection standards than your country, appropriate Safeguards (such as contracts and technical Security measures) will be adopted to protect and maintain the confidentiality of your data.

d. How long will my coded data be kept?

The study site and the sponsor are obliged to keep all study data for a number of years to comply with study site's and Sponsor's legal obligations. You can find out more about how the sponsor keeps personal information at www.astrazenecapersonaldataretention.com. Your coded data will then be deleted or anonymised.

e. What are my rights under data protection law?

Subject to local laws, *y*ou have the right to review which of your data are collected and being used;

To ensure the scientific integrity of the study, you will not be able to review some of the data or receive a copy of it until the study ends.

f. What does anonymised data mean?

Health authorities as well as pharmaceutical companies believe that access to clinical studies data advances clinical science and medical knowledge and is in the best interest of patients and public health, provided that patient privacy is protected. Therefore, the

sponsor may generate and share internally or with other researchers an anonymised set of your data collected in the study (e.g., on www.clinicalstudydatarequest.com). This means your coded data will be stripped of your Patient code as well as of any other information that could reasonably be used to identify you such as your date of birth.

9 What are the costs of taking part?

Participating in this study will not cost you anything more than the costs related to your routine appointments with your doctor. You will not be paid for being in this study.

You may be reimbursed for reasonable expenses incurred due to your participation in the study (for example: travel). If so, you will be paid RMB 150 per visit per protocol.

10 What will happen if I want to quit the study?

Your participation in the study is voluntary which means you can stop your participation at any time. If you want to stop your participation, you should tell the study doctor.

If you stop participating in the study, the study doctor will stop the collection of your data but your previously collected data will be kept and used to guarantee the validity of the study and comply with regulatory requirements, as allowed by law. The study doctor will then invite you to have an end of study examination to check your wellbeing. If you don't show up at a planned visit, the study doctor will try to reach you. If the study doctor cannot reach you, public sources will be consulted to verify your wellbeing. This is important for study results. It is not mandatory but would be helpful for the study if you explain to your study doctor why you wish to stop your participation, in particular if you have experienced discomforts.

If you would like your data not to be used after you quit the study, you must inform the study doctor. In such case, your coded data previously collected will be kept as required by clinical regulations.

11 Who can answer any questions I may have?

Shanghai Jiaotong University School of Medicine, Renji Hospital Ethics Committee has reviewed the plans for this study to make sure that people who take part in this study are protected from harm.

If you have any questions about your rights during your taking part in this study, you can contact:

< Qi Lu, 021-58752345 , Dongfang Road 1630, Shanghai, China >

If you have any questions about the study, please contact:

Study doctor Haijiao Jin	Study Coordinator (e.g. nurse appointed to the study) <*insert details*>
Phone No. 13917735313	Phone No. <*insert details*>
Address Dongfang Road 1630, Shanghai, China	Address <*insert details*>

12 How to find out more after the study?

Information about this study will be posted on http://astrazenecaclinicaltrials.com and http://www.clinicaltrials.gov. These websites do not contain any information about you. You can visit this website for more information. You may also get other information about your participation in the study from Sponsor via your study doctor.

PART 2: FUTURE RESEARCH INFORMATION

In addition to participating in the study, we would like to know if you would be willing that your coded data are used in future research projects with appropriate ethical approval.

You are free to consent to the use of your coded data for future research. If you decide not to do so, you may still take part in the clinical study.

1 What is future research?

Future research is important to advance science and public health. At present, however, it is not possible to foresee all details of future scientific research projects. These future scientific research projects are beyond the scope of the study and use of data as outlined in part 1 and may occur whilst the study is ongoing or after the study has finished.

Your coded data may only be used for scientific health-related research to find new ways to detect, treat, prevent or cure health problems.

They may also be used jointly with information from other sources outside typical clinical research settings, e.g. from public research databases. However, they will not be combined with other information in a way that could identify you. Your coded data and may also be anonymized for some of the future scientific research.

2 May my coded data be shared?

The sponsor may share your coded data with research partners. This may include researchers from research hospitals, and companies.

Some of the above-mentioned recipients may be located outside your country. The data protection laws which apply in those countries may not be as stringent as the laws in your country. Nevertheless, appropriate safeguards and security measures will be taken in order to protect and maintain the confidentiality of coded data.

3 How will my privacy be protected?

Your coded data will be subject to appropriate safeguards, and will only be used for the purpose of scientific health related research. They will not be used to contact you or to affect your care or any other decision affecting your life such as insurance rates or employment opportunities.

4 What if I want to withdraw from future research?

Your participation in future research is voluntary. You are entitled to withdraw your consent for future research at any time, without giving a reason and without a negative effect on your standard of medical care. If you wish to withdraw, please inform your study doctor.

You may still continue to participate in the research study even if you choose to withdraw from future research.

If you withdraw from future research, your coded data will not be used for future research. Your coded data (either copied from the research study database or newly generated) will also be destroyed unless this information is already included in analyses or used in scientific publications or if the coded data been anonymized and therefore we can't identify your data.

5 Results from Future Research?

We may have to study coded data from many people over many years before we can know if the results of future research are meaningful.

Therefore, you should not expect to receive individual results from future research projects. We will not give any such data to your doctor and we will not put them in your medical record as they are not individual valid results.

You are free to consent to the use of your coded data for FUTURE RESEARCH. If you disagree, you can indicate this in the CONSENT FORM.

PART III: CONSENT FORM

Study Code:	D9480R00033	Site No:	
Sponsor:	AstraZeneca China	Investigator:	
Study Title:	Hyperkalaemia Prevalence, Recurrence and Treatment in Haemodialysis: A prospective multi-centre cohort study		

I confirm that:

- The study doctor or study personnel delegated by the study doctor has explained the study to me comprehensively.
- I have had the opportunity to discuss the study with the study doctor and all my questions were answered.
- I have had an adequate amount of time to consider the study.
- I have read and understood all the above information related to the study.
- I understand that I will receive a copy of this document once I have signed it.
- I understand that my decision to take part in the study is entirely voluntary. If I decide not to participate in the study or to stop my participation during the study, this will not affect my standard medical care.
- I have truthfully answered all questions about my medical history and will follow all rules listed in the document.

I consent to take part in the research study and study procedures described herein. I understand that my participation also entails:

- My name and contact details being collected during the study as described to me, and accessed and reviewed by listed authorised people;
- My coded data being used by the sponsor or by people or companies acting on its behalf or working with the sponsor;
- My coded data being used by persons or organisations located in countries that do not have data protection rules equivalent to those of my country. I understand that the sponsor monitors these uses and takes all possible measures to protect my privacy;

SIGNATURE CONSENT FORM

Signature of participant	Date of Signature
Printed name of participant	
Signature of person conducting the informed consent discussion	Date of Signature
Printed name of person conducting the informed consent discussion	

Please complete the following if legally accepted representative or impartial witness is applicable.

Signature of legally accepted representative	Date of Signature
Printed name of legally accepted representative	
Relationship of legally accepted representative to participant	
Signature of impartial witness	Date of Signature
Printed name of impartial witness	

When signed and dated, we will give you a copy of this form.

PART IV: ADDITIONAL INFORMATION FOR PATIENTS

1 Sponsor details:

Sponsor details	Sponsor: AstraZeneca Investment (China) Co., Ltd, No.199 Liangjing Road Shanghai 201203, China The sponsor has the overall responsibility for the research study.

2 Detailed list of visits and Test/Procedures

	Visit 1	Visit 2	Visit 3	Visit 4	Visit 5	Visit 6	Visit 7	Visit 8
	day 1	day 3 or 5	week 4	week 8	week 12	week 16	week 20	week 24
Pre-dialysis serum K^+	X	X	X	X	X	X	X	X
Post-dialysis serum K^+	X							
Pre-dialysis BUN & Post-dialysis BUN	X				X			
Blood Sample Collectionroutine	X		X	X	X	X	X	X
Blood Biochemistry measurements	X		X	X	X	X	X	X
Blood gas analysis	X		X	X	X	X	X	X
Urine 24- hour volume & Urine samplebiochemistry test			X	X (if not done at visit 3)				