CLINICAL TRIAL PROTOCOL

ASSESSMENT OF THE **I**NCREMENTAL **H**AEMO**D**IALYSIS SECURITY AND EFFECTIVENESS IN **I**NCIDENT **P**ATIENTS

PROTOCOL CODE

Trial IHDIP

VERSION:

2nd version of March 10th 2017

SPONSOR and COORDINATOR/INVESTIGATORS:

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This project has the endorsement of the Extremadura Health and Social Policy Council and also of the Spanish Society of Nephrology

IINFORMED CONSENT

Hemodialysis modality:	
Progressive hemodialysis	
Conventional hemodialysis	

1. Hospital: _____
2. Service/Unit_____
3. Doctor: _____
4. Patient: _____
5. ID: _____
6. Representative:
7. ID: _____

The document is intended to verify that you, or whoever represents you, have received verbal (and in writing) adequate and understandable information, including the purpose and nature of the above procedure, its risks and consequences. As with any action in the field of health, for the accomplishment of Hemodialysis (Progressive or Conventional) also requires the free and voluntary consent of the patient, once all the information has been received and evaluation according to national and international regulation have been carried out.

I DECLARE: That the Doctor ..... has explained to me that performing regular HEMODIALYSIS sessions is convenient and necessary in my situation, that I have adequately understood the information given and that I am satisfied with the information received. I have been able to formulate the questions that I thought fit, and that have clarified all the doubts raised. I hereby consent, free and voluntary, to perform the prescribed hemodialysis sessions. I have also been informed of the possibility of anonymously using the results obtained with this procedure, its statistical processing and its scientific dissemination in the usual means as part of a research project in patients on hemodialysis that maintain renal function (Study IHDIP) and that in no case may it pose an additional risk to my health.

In *(place)*..... at *(date)*..... del 201..

Signed
Miss/Mrs/Mr/Ms.....ID.....

ADDITIONAL INFORMATION ATTACHED TO THIS CONSENT

Your doctor has diagnosed you with a condition called advanced chronic kidney disease. Irreversibly, your kidneys do not perform their function effectively and as a result do not purify the blood of substances that are dangerous to life, nor are there other ones that are essential. Therefore, it is not possible to live without an organ that develops all these important functions. For this reason, his nephrologist believes that he must initiate a treatment that is known as hemodialysis (HD), which tries to supply, but only partially, some of the functions of his kidneys.

Dialysis consists of cleaning the blood, allowing the passage of water and substances contained in it, through a specific filter, which we call the dialyser, made a liquid for its elimination. This results in prolonged survival, which depends to a great extent on the age and associated diseases of the patients. Hemodialysis is usually well tolerated although occasional side effects may occur. Some common but not very serious:

1. Nausea, vomiting, headache, hypotension, cramps.
2. Hematomas or small blood loss from the puncture points or from a breakdown of the dialyzer.
3. Other uncommon but more serious as cardiac abnormalities such as arrhythmias, angina pectoris, or strokes, severe allergic reactions, or rupture of red blood cells (hemolysis). The latter could endanger your life in a very exceptional way.
4. In some cases, infectious complications may occur, due to the reduction of the hemodialysis patient's defenses, or to the manipulation of blood, and to the patient's contact in hospital settings. They are usually due to bacteria or viruses, and can cause hepatitis B and C.
5. There are other complications related to vascular access that occur in the form of hemorrhages, thrombosis, infections and, exceptionally, their rupture, involving medical rescue techniques and procedures.

As for the number of sessions per week of the same, we can say that their number is one that allows to improve the quality of life of the patient with the renal replacement technique. For this, several clinical guidelines recommend, based on the evidence, the dose and frequency of sessions. The KDOQI1 (International Hemodialysis Guide) recommends a minimum dose, measured by Kt / V of 1.2 for patients prevalent in the 3-week anuric session mode, but opens the door to adjust it conditioned to the existence or non-existence of function Renal residual. That is, if you urinate more than 500 milliliters a day and the elimination of toxins from your kidneys is higher than 2.5 ml / min, measured by your reference nephrologist (according to validated formulas), is a candidate, if there are no diseases that contraindicate to enter a HD session a week, unlike the usual pattern of 3 sessions. We rely on promising studies, which emphasize that starting hemodialysis once or twice a week versus three times a week, preserves residual renal function, with no associated complications. Furthermore, this residual renal function has been correlated with a decrease in morbidity and mortality in patients on dialysis programs. The possible complications, added to the previous ones are the possibility of VOLUME OVERLOAD OR A BAD CONTROL OF THE BASE-ACID BALANCE AND / OR THE HYPERPOTASEMIA. For this reason, it is important to monitor the patient's weight gain and the ultrafiltration rates necessary for maintenance. As well as necessary biochemical and gasometric controls (fortnightly or earlier) if a possible complication is suspected.

You have also been informed of your right to request additional information in case you need it, and that no additional procedure, other than those of which you have been informed, is given to you, for which you have given your consent, unless it is strictly necessary to save your life or to avoid some irreparable damage to your health. Finally, in compliance with the Law on the protection of personal data (*check national regulations*) we inform you that the information obtained in the healthcare of your person has been incorporated for treatment to an automated file. It is also informed that the collection

and treatment of these data are aimed at the epidemiological, scientific and educational study, respecting at all times their anonymity. If you wish, you can exercise the rights of access, rectification, cancellation and opposition, provided by law.

CONSENT REVOCATION

I revocate the consent given on ……. of …… of 201__ .

I do not want to continue with the treatment that I give on this date by finished.

In *(place)*..... at *(date)*..... del 201..

Signed
Miss/Mrs/Mr/Ms.....ID.....