HAEMODIALYSIS TREATMENTS
DOMAIN PARTICIPANT INFORMATION SHEET

Title:	Better Evidence And Translation for Calciphylaxis (BEAT-Calci)
Investigators:	Prof Meg Jardine (Co-ordinating Principal Investigator) *[Name]* (Principal Investigator) *[Name]* (Associate Investigator) *(if required by institution)*
Study Sponsor:	The University of Sydney
Coordinating Centre:	NHMRC Clinical Trials Centre
Site:	[Site name] (where PI will recruit)

1 Which haemodialysis treatments are being tested?

Changing the dialysis prescription is one treatment approach used by kidney doctors to manage calciphylaxis. This includes making changes to the type of filter used during dialysis. When you have kidney failure, your body cannot get rid of waste chemicals, salt, and extra water. Dialysis cleans the blood, which is part of the work that your kidneys usually do for you. In haemodialysis, your blood is taken out of your body via tubing and passed through a special filter, also known as a 'dialysis membrane'. This filter cleans your blood by removing waste. Blood is then returned clean to your body.

It is common for certain chemicals to build-up in the blood in kidney failure. Some of these chemicals are known as "middle molecules" which can lead to inflammation and a build-up of calcium in the blood. Both of these changes can lead to the development of calciphylaxis.

The standard of care for dialysis varies across Australia but all filters used in this study are standard for at least one hospital in Australia. In this study, two dialysis membranes (filters) will be compared for their effect on calciphylaxis and wound healing. Your study team may refer to these treatment types as a 'dialysis membrane domain'.

a) Medium Cut-Off haemodialysis

Medium Cut-Off haemodialysis (MCO HD) uses a new type of dialysis membrane, called a Medium Cut-Off membrane. This membrane has a larger pore size compared to the standard dialysis membrane. This allows for better removal of middle molecules. Removing these chemicals may stop or reduce the processes that cause or prolong calciphylaxis.

b) High flux haemodialysis

High flux haemodialysis (HD) is the standard form of haemodialysis treatment that is used in most centres worldwide. As you have kidney failure, you may already be receiving HD treatment as your dialysis treatment.

2 What happens at the beginning of the study and during follow-up?

If you choose to take part, you will be randomly allocated (like rolling a dice) to one of two treatment options: MCO HD treatment (intervention) or HD treatment (control). With either treatment, your dialysis will be conducted as usual, according to your treating doctor. You and your study team will know which treatment you are receiving throughout the study.

3 What happens if my condition is not improving?

If your calciphylaxis condition does not improve within the first 12 weeks of you taking part in the study, your study doctor will ensure that you receive MCO HD treatment (the intervention) for the remainder of the study.

4 What if I miss a treatment?

It is very important that you inform your study doctor and the study team if you are unable to attend the hospital to receive your dialysis treatment. Missing dialysis can lead to waste build-up in the body and make you very unwell. Your study team will make a note of any missed sessions or frequency changes to your dialysis routine throughout the study.

5 What are the possible side effects?

Haemodialysis can be associated with symptoms in some people at some times. These symptoms include feeling sick, tired, dizzy, nauseous, or having muscle cramps. These symptoms will not be further affected by MCO HD treatment (the intervention), and no known additional side effects from this treatment have been identified in recent studies.

6 Could my treatment be stopped unexpectedly?

There are some circumstances where your study doctor may recommend modifying the study treatment, such as changing frequency of dialysis. If MCO HD treatment (the intervention) is permanently stopped, you can still continue to be a part of the study and will be encouraged to attend follow-up visits.

At any time throughout the study, you can choose to stop the study treatment should you wish but please discuss this more with your study doctor, so they are aware.

At the end of your follow-up in this study, your treating doctor at the time may choose to continue to use HD or MCO HD treatment but this will be discussed with you.

7 Who is organising and funding the research?

This study domain is coordinated by the NHMRC CTC and sponsored by University of Sydney.

Principal funding is through the Australian Government's Medical Research Future Fund. Baxter Health is providing some financial support for this study domain. Baxter Health may benefit financially from this study domain if, for example, positive results are demonstrated.

The study site will receive a payment from the NHMRC CTC for undertaking this study domain.

No member of the study team will receive a personal financial benefit from your involvement in this study domain (other than their ordinary wages).