Screening period
4–5 weeks

To check if the study is right for you and to see if you want to take part.

2 visits

The investigational drug is given during your routine hemodialysis treatment.

Study treatment period
Two periods of 12 weeks

You will visit the study center **3 times per week** for your routine hemodialysis sessions, study assessments, and to receive:

- investigational drug or placebo (first 12 weeks)
- investigational drug (following 12 weeks)

Follow-up period
About 4 weeks

1 study visit

Is the CALCIPHYX Study right for you?

The answer may be yes, if you:

- are an adult patient on hemodialysis who has at least 1 painful calciphylaxis wound
- have not received bisphosphonates (medications that help prevent or slow down bone thinning) in the past 3 months
- are not expecting to have a kidney transplant within the next 6 months
- adhere to your hemodialysis treatments.

Talk to your study doctor about other criteria required for you to take part.

Find out more

If you have any questions, you can contact the study team using the information provided below.

- There is no cost or obligation to take part.
- Consult with your doctor about the possible risks and benefits of participating.
- Visit ClinicalTrials.gov NCT04195906 for additional information.

InfoCUAtrial@Sanifit.com

Participant Brochure, 15 Apr 2020 [V01 USA01]

CALCIPHYX

Together, let's work towards a treatment option for wounds in patients on dialysis

Help us research an investigational drug that might help patients with calciphylaxis

Research Study Information

What is a clinical trial or clinical research study?

A clinical trial is a medical research study. It is conducted to determine if an investigational drug is safe and if it works. Health authorities, such as the US Food & Drug Administration (FDA) or the European Medicines Agency (EMA), oversee the medical research study. Participation is always voluntary.

The CALCIPHYX Study of SNF472

SNF472 is an investigational drug given during hemodialysis.

The aim of the CALCIPHYX Study is to:

- evaluate if SNF472 works to treat calciphylaxis wounds in patients who are on hemodialysis
- evaluate the safety of SNF472.

SNF472 is given in addition to regular calciphylaxis wound care and pain medication.

We are looking for people to take part in the CALCIPHYX Study.

What will happen during the CALCIPHYX Study?

In the CALCIPHYX Study, 66 participants will:

- be supported by a team of medical professionals (the study team)
- have study-related tests and assessments at specific times
- continue to receive usual hemodialysis care, wound care, and pain medications.

66

All aspects of the CALCIPHYX Study have been approved by an Ethics Committee that ensures the rights of study participants are protected.

What does SNF472 do?

SNF472 has been designed to slow the formation of calcium crystals in the small blood vessels. By slowing the growth of these calcium deposits, it is hoped that SNF472, together with the regular care for calciphylaxis, may help to:

- improve wound healing
- reduce wound pain.

SNF472 has already been taken by more than 200 participants on hemodialysis and was generally well tolerated in previous clinical research studies. SNF472 is not approved for use outside of this clinical research study.

What does the study involve?

All participants in the study will:

- receive their regular care and pain medications for wounds
- continue routine hemodialysis sessions during the study treatment period.

During the first 12 weeks of the 24-week study treatment period:

- half of the participants will receive the investigational drug
- the other half will receive placebo, which looks the same as the investigational drug but contains no actual medication.

Participants who complete the first 12 weeks will receive the investigational drug for the following 12 weeks.