

The UK Calciphylaxis Study

Submission date 22/03/2012	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 24/09/2012	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 14/10/2022	Condition category Urological and Genital Diseases	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Calcific uraemic arteriopathy or calciphylaxis is a disease caused by the build-up of calcium on the walls of the small blood vessels which supply the skin and/or muscle. This leads to reduced blood flow causing rashes, ulcers and pain in the affected tissues. It commonly affects the legs and arms but can affect the torso, back or breasts. It occurs almost exclusively in patients with chronic kidney disease but remains very rare, with about 1 case per year for every 600 dialysis patients in the UK. The trigger for the disease is not known but may include local injury. There is no specific treatment as yet that has been shown to work in many or most cases. Doctors often concentrate on getting the balance of minerals in the body right (e.g., calcium and phosphate control). This may require changing dialysis regimes, changing medications or considering treatment for overactive parathyroid glands. In addition, health-care teams focus on pain control, good nutrition and excellent ulcer care if the skin has broken down. This collaborative research project with the UK and Germany aims to find out if there is anything in their treatment or previous blood tests to help us identify who may be at risk of calciphylaxis.

Who can participate?

Anyone over the age of 18 with a diagnosis of chronic kidney disease and calciphylaxis can be entered into the study.

What does the study involve?

We will collect clinical information from the patients including details of their treatment and any other diseases they have, and we will collect blood and tissue samples (skin biopsy) to diagnose the condition.

What are the possible benefits and risks of participating?

The tests we will carry out will help increase our understanding of what the disease process is, so that we can improve our treatments in the future..

Where is the study run from?

Salford Royal NHS Foundation Trust (UK).

When is the study starting and how long is it expected to run for?

The study started in March 2012 and will run until September 2026.

Who is funding the study?

This independent study was designed by clinicians and has been funded by Amgen (UK).

Who is the main contact?

Dr Smeeta Sinha

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Contact information

Type(s)

Scientific

Contact name

Dr Smeeta Sinha

Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

11704

Study information

Scientific Title

The UK Calciphylaxis Study: a cohort study

Study objectives

Calciphylaxis is a rare condition which results in small arteries becoming calcified. This results in painful ulceration of the skin which in turn can result in infection and further damage to tissue. It is associated with a high mortality rate (60-80%).

Consequently research into this area is important. The aims of this study are to determine the following:

1. What is the natural history of the disease?

2. What risk factors are associated with development and progression of calciphylaxis?
3. Which treatments currently in clinical practice confer a favourable outcome?
4. What are the underlying disease processes?

These aims will be achieved by collecting information on medications, clinical parameters, local laboratory tests, measuring specific proteins and molecules in blood and tissue as well as studying patients DNA profiles.

More details can be found at <http://public.ukcrn.org.uk/search/StudyDetail.aspx?StudyID=11704>

Ethics approval required

Old ethics approval format

Ethics approval(s)

First MREC 12/09/2011, ref: 11/NW/0528

Study design

Observational cohort study

Primary study design

Observational

Secondary study design

Cohort study

Study setting(s)

Hospital

Study type(s)

Diagnostic

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Chronic kidney disease/ calciphylaxis

Interventions

Baseline clinical information on comorbidity, renal replacement therapy (RRT), medications, standard laboratory variables, skin lesions and diagnosis.

Plasma/Serum and clotting samples will be taken at baseline, week 1 and 2, 1 month and after full healing should this occur. Samples will be tested for serum levels of promoters and inhibitors of calcification, and clotting factor deficiencies. A DNA sample will be taken at baseline. Four monthly follow-up clinical and laboratory data collection until full recovery or death. Final bloods will be taken after full healing should this occur.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Plasma/Serum and clotting samples measured at baseline, week 1 and 2, 1 month

Secondary outcome measures

No secondary outcome measures

Overall study start date

01/03/2012

Completion date

30/09/2026

Eligibility

Key inclusion criteria

1. Male and female, age more than equal to 18 years
2. Any patient with chronic kidney disease
3. Clinical diagnosis of calciphylaxis
4. Informed consent

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

UK Sample Size: 200

Key exclusion criteria

Patients who cannot give informed consent

Date of first enrolment

01/03/2012

Date of final enrolment

01/09/2021

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Department of Renal Medicine

Salford

United Kingdom

M6 8HD

Sponsor information

Organisation

Salford Royal NHS Foundation Trust

Sponsor details

Clinical Sciences Building

Stott Lane

Salford

England

United Kingdom

M6 8HD

Sponsor type

Hospital/treatment centre

Website

<http://www.srft.nhs.uk/>

ROR

<https://ror.org/019j78370>

Funder(s)

Funder type

Industry

Funder Name

Amgen (UK)

Alternative Name(s)

Amgen Inc., Applied Molecular Genetics Inc.

Funding Body Type

Government organisation

Funding Body Subtype

For-profit companies (industry)

Location

United States of America

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal.

Intention to publish date

01/09/2022

Individual participant data (IPD) sharing plan

All data generated or analysed during this study will be included in the subsequent results publication.

IPD sharing plan summary

Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Interim results article		01/10/2021	14/10/2022	Yes	No