

# Influence of successful periodontal intervention on renal disease

|                                        |                                                   |                                                                                                              |
|----------------------------------------|---------------------------------------------------|--------------------------------------------------------------------------------------------------------------|
| <b>Submission date</b><br>22/04/2015   | <b>Recruitment status</b><br>No longer recruiting | <input type="checkbox"/> Prospectively registered<br><input checked="" type="checkbox"/> Protocol            |
| <b>Registration date</b><br>23/04/2015 | <b>Overall study status</b><br>Completed          | <input type="checkbox"/> Statistical analysis plan<br><input type="checkbox"/> Results                       |
| <b>Last Edited</b><br>07/03/2023       | <b>Condition category</b><br>Oral Health          | <input type="checkbox"/> Individual participant data<br><input type="checkbox"/> Record updated in last year |

## Plain English summary of protocol

### Background and study aims

Patients with chronic kidney disease (CKD) may also have a common, bacterial inflammatory condition affecting the gums (periodontitis). The effects of periodontitis are not limited to the mouth but spread to other sites in the body via bleeding gums during eating, talking or brushing. Periodontitis is easily treatable using a mix of professional cleaning by a dentist or hygienist and improved homecare on the part of the patient. In an ongoing study being carried out in Birmingham, we have found that periodontitis might have a deleterious effect on the general health of patients with CKD. Given that periodontitis is readily treatable and that the treatment of periodontitis may have a beneficial effect on patients, the aim of this study is to test the practicality of conducting a larger-scale study to investigate the effect of treating periodontitis on the general health of patients with CKD.

### Who can participate?

Patients aged 18 and over with periodontitis. To be included in group 1 (see below) the patients also have to have CKD.

### What does the study involve?

Patients with CKD and periodontitis are randomly allocated into one of two groups. Those in group 1 receive intensive treatment for their periodontitis at the Birmingham Dental Hospital. The effects of this treatment on the general health of patients with CKD are assessed by comparing these patients to patients randomly assigned to the other group who receive this intensive treatment but after a delay of 12 months. All patients are followed up for 18 months.

### What are the possible benefits and risks of participating?

Not provided at time of registration

### Where is the study run from?

Birmingham Dental Hospital (UK)

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

January 2015 to April 2024

Who is funding the study?

1. Kidney Disease UK
2. National Institute for Health Research (UK)

Who is the main contact?

Mr Praveen Sharma

## Contact information

### Type(s)

Scientific

### Contact name

Mr Praveen Sharma

### ORCID ID

<https://orcid.org/0000-0001-6435-4842>

### Contact details

Birmingham Dental Hospital  
St Chad's Queensway  
Birmingham  
United Kingdom  
B4 6NN

## Additional identifiers

### Protocol serial number

18458

## Study information

### Scientific Title

Influence of successful periodontal intervention on renal and vascular systems in patients with chronic kidney disease: a pilot interventional randomised controlled trial

### Acronym

INSPIRED

### Study objectives

The overarching research question which this pilot will contribute to answering is: In patients with Chronic Kidney Disease (CKD) and periodontitis, does the intensive treatment of periodontitis and maintenance of periodontal health, compared with the current, community-care standard of periodontal therapy, have an impact upon renal and cardiovascular health?

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

## **Study design**

Randomised; Interventional; Design type: Treatment

## **Primary study design**

Interventional

## **Study type(s)**

Treatment

## **Health condition(s) or problem(s) studied**

Topic: Oral and dental health, Renal disorders; Subtopic: Renal disorders, Oral and dental public health; Disease: All Oral and dental health, All Renal disorders

## **Interventions**

Intensive periodontal treatment, oral hygiene instructions, supra and sub gingival scaling and non-surgical root surface debridement followed by periodontal maintenance therapy

Study Entry : Registration and One or More Randomisations

## **Intervention Type**

Procedure/Surgery

## **Primary outcome(s)**

As this is a pilot study, the primary objective will be informing a definitive trial to follow. The feasibility/pilot objectives include:

1. Investigating the integrity of the study protocol
2. Insight into likely recruitment rates and barriers to recruitment
3. Testing delivery of patient questionnaires and the randomisation process
4. Assessing the acceptability of the intervention
5. Collection of pilot data on effect size and variability
6. Selection of suitable primary and secondary outcomes (from the outcomes of interest listed below) and subsequent sample size calculation for a pivotal trial.

The outcomes of interest include:

1. Measures of renal function
2. Measures of cardiovascular function
3. Measures of periodontal health
4. Patient-centred outcomes

## **Key secondary outcome(s)**

No secondary outcome measures

## **Completion date**

30/04/2024

# **Eligibility**

## **Key inclusion criteria**

Inclusion criteria for all participants:

1. Patient aged  $\geq 18$  years and
2. Be able to provide consent to participate in the trial

Additional inclusion criteria for patients with CKD and periodontitis:

1. Secondary care renal follow up for at least 1 year prior to recruitment
2. Decline of eGFR of 5mls/min/year or 10mls/min/5years
3. And/or an Albumin Creatinine Ratio (ACR)  $> 70$ mmol/l on three occasions
4. And/or CKD 4 or 5 (pre-dialysis)
5. And generalised moderate-severe periodontitis defined as a minimum cumulative probing depth of 30mm (excluding probing depths  $< 5$ mm)

Additional inclusion criteria for systemically healthy patients with periodontitis:

1. Generalised moderate-severe periodontitis defined as a minimum cumulative probing depth of 30mm (excluding probing depths  $< 5$ mm)

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Lower age limit**

18 years

### **Sex**

All

### **Total final enrolment**

77

### **Key exclusion criteria**

Exclusion criteria for all participants:

1. Not meeting the inclusion criteria
2. Unable to provide informed consent

Additional exclusion criteria for patients with CKD and periodontitis:

1. Requiring Renal Replacement Therapy (dialysis/transplant)
2. Immunosuppression
3. Received specialist periodontal treatment in the past 1 year
4. Not amenable to periodontal treatment e.g. severe bleeding disorders that contraindicate periodontal treatment

Additional exclusion criteria for systemically healthy patients with periodontitis:

1. Any self-reported systemic illness eg hypertension or diabetes
2. Received specialist periodontal treatment in the past 1 year
3. Not amenable to periodontal treatment e.g. severe bleeding disorders that contraindicate periodontal treatment

Additional exclusion criteria for systemically healthy patients without periodontitis:

1. Any self-reported systemic illness eg hypertension or diabetes
2. Periodontitis defined as probing depth of >4mm at any site

**Date of first enrolment**

26/02/2015

**Date of final enrolment**

30/04/2018

## **Locations**

**Countries of recruitment**

United Kingdom

England

**Study participating centre**

**Birmingham Dental Hospital**

School Of Dentistry

St Chad's Queensway

Birmingham

United Kingdom

B4 6NN

## **Sponsor information**

**Organisation**

University of Birmingham

**ROR**

<https://ror.org/03angcq70>

## **Funder(s)**

**Funder type**

Government

**Funder Name**

Kidney Research UK

**Alternative Name(s)**

**Funding Body Type**

Private sector organisation

**Funding Body Subtype**

Trusts, charities, foundations (both public and private)

**Location**

United Kingdom

**Funder Name**

National Institute for Health Research

**Alternative Name(s)**

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

**Funding Body Type**

Government organisation

**Funding Body Subtype**

National government

**Location**

United Kingdom

## Results and Publications

**Individual participant data (IPD) sharing plan**

There are currently no plans to share pseudoanonymised IPD.

**IPD sharing plan summary**

Not expected to be made available

**Study outputs**

| Output type                          | Details  | Date created | Date added | Peer reviewed? | Patient-facing? |
|--------------------------------------|----------|--------------|------------|----------------|-----------------|
| <a href="#">Protocol article</a>     | protocol | 13/11/2017   |            | Yes            | No              |
| <a href="#">HRA research summary</a> |          |              | 28/06/2023 | No             | No              |