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Influence of successful periodontal intervention on renal disease

Submission date 22/04/2015	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 23/04/2015	**Overall study status** Completed	
Last Edited 07/03/2023	**Condition category** Oral Health	

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
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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)

West Midlands – The Black Country Research Ethics Committee, 08/01/2015, ref: 15/WM/0006

Primary study design
Interventional

Study design
Randomised; Interventional; Design type: Treatment

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 ≥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)>70mmol/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 <5mm)

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 <5mm)

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
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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?
Protocol article	protocol	13/11/2017		Yes	No
HRA research summary			28/06/2023	No	No