

A feasibility study to inform the design of a national multi-centre RCT to evaluate if reducing serum phosphate to normal levels improves clinical outcomes including mortality, cardiovascular events, bone pain or fracture in patients on dialysis

Submission date 16/01/2014	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 16/01/2014	Overall study status Completed	☒ Protocol
Last Edited 10/02/2020	Condition category Urological and Genital Diseases	☐ Statistical analysis plan
		☒ Results
		☐ Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
14591

Study information

Scientific Title

A feasibility study to inform the design of a national multi-centre RCT to evaluate if reducing serum phosphate to normal levels improves clinical outcomes including mortality, cardiovascular events, bone pain or fracture in patients on dialysis

Acronym

SPIRiT

Study objectives

Dialysis patients have a very high death rate; circumstantial evidence suggests this may be related to increased levels of phosphate in their blood, but conclusive evidence is lacking. There is currently no definite proof that reducing blood levels of phosphate is beneficial to dialysis patients. Therefore discussions between clinicians and patients lack a sound evidence base. Existing methods of reducing phosphate levels require control of diet/food intake, swallowing large numbers of unpalatable large tablets and/or lengthening the time of dialysis treatments. Consequently patients (and clinicians) have identified phosphate self-management as complicated and difficult, and are unsure how worthwhile it is to their long-term health. A large randomised controlled trial (~3000 patients randomised 50:50 to either lower phosphate or higher phosphate ranges for 3+ years) is required to answer the key question "Would reducing phosphate levels improve the length of dialysis patients' lives?" However, whether such a trial is technically possible is unknown, and therefore we are conducting a feasibility study (120 patients over 24 months) to inform the design and conduct of a future, definitive trial. This feasibility study will assess:

1. The effectiveness of a stepped approach to achieving 'lower/normal' serum phosphate levels, and the possibility of achieving clear separation by serum phosphate between the 'lower range' and 'higher range' groups.
2. Willingness of patients to be randomised,
3. Willingness of clinicians to recruit participants in a trial that includes 'higher range' serum phosphate control are they convinced that this is acceptable?
4. The symptoms scores for each group.
5. Likely number of eligible patients, recruitment timescale and drop-out rates.

The outcome of this feasibility study will be used to design the larger multicentre study; its results will have major implications for self-management by dialysis patients.

Ethics approval required

Old ethics approval format

Ethics approval(s)

13/EM/0052

Study design

Randomised; Interventional; Design type: Process of Care, Treatment

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Topic: Renal and Urogenital; Subtopic: Renal and Urogenital (all Subtopics); Disease: Renal

Interventions

Communicare: This is a self help computer package to encourage adherence to oral phosphate binders.

Dietician review: This is done in the washout period

Modified BAASIS: This is a questionnaire which is administered every 4 weeks in the study to encourage adherence

Oral phosphate binders: These are Lanthanum and Sevelamer. They are normally used as part of routine clinical care in dialysis patients.

PDSI: Pittsburgh Dialysis Symptom Index - This is a symptom score which is administered at 3 time points in the study.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

Feasibility; Timepoint(s): End of the study - Is a large national multi-centre RCT feasible?

Key secondary outcome(s)

1. Adherence; Timepoint(s): End of the study
2. Consent; Timepoint(s): End of the study - Percentage Suitable Vs Percentage consented
3. Drop out rate; Timepoint(s): End of the study
4. Event rate; Timepoint(s): End of the study
5. Pill burden; Timepoint(s): End of the study
6. Renal physicians; Timepoint(s): End of the study - Percentage of renal physioicians willing to let their patients enroll
7. Suitability; Timepoint(s): Percentage of total dialysis population found suitable - End of the study
8. Target Phosphate; Timepoint(s): End of the study - Percentage who achieved target serum phosphate

Completion date

31/12/2016

Eligibility

Key inclusion criteria

1. Male and female patients aged 30 years or above, on dialysis for at least 6 months, under the supervision of Central Manchester University Hospitals Foundation Trust (CMFT) or Salford

Royal NHS Foundation Trust (SRFT)

2. Serum phosphate level of 1.8mmol/L or greater after washout (discontinuation) of previous phosphate binding medication
3. Able to achieve Renal Association standards for quality of dialysis
4. Able to communicate in English ('Communicare' package is available only in English)
5. Able to consent

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Total final enrolment

104

Key exclusion criteria

1. Living donor renal transplant planned in the next 12 months
2. Serum parathyroid hormone greater than 800 pg/ml (85 pmol/L) on 2 consecutive 3-monthly blood tests. Such patients probably have uncontrolled hyperparathyroidism which adversely influences serum phosphate levels, and needs treatment in its own right
3. Known intolerance of oral sevelamer and lanthanum carbonate
4. Medical history that might limit the individual's ability to take the trial treatments for the duration of the study (e.g. history of cancer other than non-melanoma skin cancer, or recent history of alcohol or substance misuse)
5. Patients aged below 30 years have a low rate of vascular events and will not be recruited

Date of first enrolment

27/05/2013

Date of final enrolment

31/03/2014

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Manchester Royal Infirmary
Manchester

United Kingdom
M13 9WL

Sponsor information

Organisation

Central Manchester University Hospitals NHS Trust (CMFT) (UK)

ROR

<https://ror.org/00he80998>

Funder(s)

Funder type

Government

Funder Name

NIHR Research for Patient Benefit (RfPB); Grant Codes: PB-PG-0711-25112

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	04/02/2019	10/02/2020	Yes	No
Protocol article	protocol	01/09/2015		Yes	No
HRA research summary			28/06/2023	No	No