ISRCTN24741445 https://doi.org/10.1186/ISRCTN24741445

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

Registration date
16/01/2014

Overall study status
Completed

Last Edited
10/02/2020

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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

Secondary outcome measures
1. Adherance; 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 physoicians 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

Overall study start date
06/03/2013

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

Age group
Adult

Sex
Both

Target number of participants
Planned Sample Size: 120; UK Sample Size: 120

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
England

United Kingdom

Study participating centre
Manchester Royal Infirmary
Manchester
United Kingdom
M13 9WL

Sponsor information

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

Sponsor details
Genetic Medicine, Manchester Royal Infirmary
Oxford Road
Manchester
England
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M13 9WL

Sponsor type
Hospital/treatment centre

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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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?
Protocol article	protocol	01/09/2015		Yes	No
Results article	results	04/02/2019	10/02/2020	Yes	No
HRA research summary			28/06/2023	No	No