ISRCTN35254279 https://doi.org/10.1186/ISRCTN35254279

Phosphate binding with sevelamer in stage 3 chronic kidney disease

Submission date	Recruitment status
29/04/2010	No longer recruiting
Registration date	**Overall study status**
29/04/2010	Completed
Last Edited	**Condition category**
01/10/2018	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

Clinical Trials Information System (CTIS)
2008-003727-23

Protocol serial number
5729

Study information

Scientific Title

Does phosphate binding with sevelamer carbonate improve cardiovascular structure and function in patients with early chronic kidney disease?

Study objectives
Does phosphate binding with sevelamer carbonate improve cardiovascular structure and function in patients with early chronic kidney disease?

Ethics approval required
Old ethics approval format

Ethics approval(s)
West Midlands Research Ethics Committee approved on the 1st October 2008 (ref: 08/H1208/37)

Primary study design
Interventional

Study design
Randomised interventional treatment trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Topic: Renal and Urogenital; Subtopic: Renal and Urogenital (all Subtopics); Disease: Renal

Interventions
Intervention: placebo or 1600 mg sevelamer carbonate with meals.

Open label: 4 - 6 weeks
Treatment (blinded) phase: 34 - 36 weeks
Total treatment time: 40 weeks
Follow up length: 10 months
Study entry: single randomisation only

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Sevelamer carbonate

Primary outcome(s)
Left ventricular mass, measured at baseline and at 40 weeks

Key secondary outcome(s)
1. Aortic compliance as measured on cardiac magnetic resonance imaging (MRI), measured at baseline and at 40 weeks
2. Arterial stiffness, measured at baseline, week 4 - 6 and at 40 weeks

Completion date
01/11/2010

Eligibility

Key inclusion criteria
1. Chronic kidney disease (CKD) patients aged 18 - 80 years, either sex
2. CKD stage 3 (glomerular filtration rate [GFR] 30 - 59 ml/min/1.73 m^2)
3. Office blood pressure (BP) controlled to less than 140/90 mmHg for 12 months before entry
4. Total cholesterol less than 5.5 mmol/L

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Existing or previous treatment within 1 year with a phosphate binder or vitamin D analogue
2. Uncontrolled hyperphosphataemia (serum phosphate greater than 1.8 mmol/L)
3. Hypophosphataemia (serum phosphate less than 0.8 mmol/L)
4. Uncontrolled secondary hyperparathyroidism (parathyroid hormone [PTH] greater than 80 pg /ml)
5. Diabetes mellitus
6. Pregnancy
7. Women of childbearing age not on contraception
8. Bowel obstruction
9. Dysphagia/swallowing disorders
10. Severe gastrointestinal motility disorders including severe constipation
11. Previous major gastrointestinal surgery

Date of first enrolment
01/04/2009

Date of final enrolment
01/11/2010

Locations

Countries of recruitment

United Kingdom

England

Study participating centre
Department of Cardiovascular Medicine
Birmingham
United Kingdom
B15 2TT

Sponsor information

Organisation
University Hospital Birmingham NHS Foundation Trust (UK)

ROR
https://ror.org/014ja3n03

Funder(s)

Funder type
Industry

Funder Name
Genzyme Corporation (UK)

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	01/04/2013		Yes	No
Protocol article	protocol	02/02/2011		Yes	No
HRA research summary			28/06/2023	No	No