

Phosphate binding with sevelamer in stage 3 chronic kidney disease

Submission date 29/04/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 29/04/2010	Overall study status Completed	<input checked="" type="checkbox"/> Protocol
Last Edited 01/10/2018	Condition category Urological and Genital Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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)

Study design

Randomised interventional treatment trial

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

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 m²)
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

