

# Phosphate binding with sevelamer in stage 3 chronic kidney disease

**Submission date**

29/04/2010

**Recruitment status**

No longer recruiting

☐ Prospectively registered

☒ Protocol

**Registration date**

29/04/2010

**Overall study status**

Completed

☐ Statistical analysis plan

☒ Results

**Last Edited**

01/10/2018

**Condition category**

Urological and Genital Diseases

☐ Individual participant data

**Plain English Summary**

Not provided at time of registration

## Contact information

**Type(s)**

Scientific

**Contact name**

Dr Colin Chue

**Contact details**

Department of Cardiovascular Medicine  
Medical School  
, Edgbaston  
Birmingham  
United Kingdom  
B15 2TT

## Additional identifiers

**EudraCT/CTIS number**

2008-003727-23

**IRAS number****ClinicalTrials.gov number****Secondary identifying numbers**

5729

# Study information

## Scientific Title

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

## Study hypothesis

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

## Secondary study design

Randomised controlled trial

## Study setting(s)

Hospital

## Study type(s)

Treatment

## Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

## Condition

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 measure**

Left ventricular mass, measured at baseline and at 40 weeks

**Secondary outcome measures**

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

**Overall study start date**

01/04/2009

**Overall study end date**

01/11/2010

## Eligibility

**Participant 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<sup>2</sup>)
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

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

Planned Sample Size: 120; UK Sample Size: 120

**Participant 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

**Recruitment start date**

01/04/2009

**Recruitment end date**

01/11/2010

## **Locations**

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

**Department of Cardiovascular Medicine**

Birmingham

United Kingdom

B15 2TT

## **Sponsor information**

**Organisation**

University Hospital Birmingham NHS Foundation Trust (UK)

**Sponsor details**

Trust Headquarters

PO Box 9551

Main Drive

Queen Elizabeth Medical Centre

Edgbaston

Birmingham

England

United Kingdom

B15 2PR

**Sponsor type**

Hospital/treatment centre

**Website**

<http://www.uhb.nhs.uk/>

**ROR**

<https://ror.org/014ja3n03>

## Funder(s)

**Funder type**

Industry

**Funder Name**

Genzyme Corporation (UK)

## 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?
<a href="#">Protocol article</a>	protocol	02/02/2011		Yes	No
<a href="#">Results article</a>	results	01/04/2013		Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No