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# Prevention of aortic stenosis pilot trial

**Submission date**
13/06/2017

**Recruitment status**
No longer recruiting

**Registration date**
13/06/2017

**Overall study status**
Completed

**Last Edited**
12/09/2019

**Condition category**
Circulatory System

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

## Plain English summary of protocol

Background and study aims
Aortic stenosis is a serious heart condition with no known means of prevention. It is caused by the build up of calcium (a mineral found in the blood) on the aortic valve (flaps of tissue which regulates blood flow) leading to obstruction of blood flow from the heart. Death follows symptoms of heart failure in most cases unless the valve is surgically replaced. The aim of this study is to determine the effect of the drug sevelamer on blood phosphate levels with a view to using this in the prevention of aortic stenosis.

Who can participate?
Adults aged 18 to 90 with mild to moderate aortic stenosis

What does the study involve?
All participants have two periods taking sevelamer (a different dose in each period) and a period taking a placebo (a dummy pill), each period lasting 6 weeks (18 weeks overall). The sequence of treatments and placebo is allocated at random. Blood and urine phosphate levels are measured at the end of each period.

What are the possible benefits and risks of participating?
This study is the first step in determining whether the progression of aortic stenosis can be prevented using sevelamer. This will help guide future medical practice both in the management of the aortic stenosis of patients participating in the study and other people with the same condition. Some people may experience side effects which are reversible on stopping treatment. These tend to be symptoms affecting the gut such as abdominal discomfort, belching, bloating, constipation, diarrhea, and feeling of fullness after eating. Major side effects are extremely rare.

Where is the study run from?
The Wolfson Institute of Preventive Medicine in London is the coordinating centre for the study where all study-related activities take place once patients have given their consent to be in the study. Patients are initially identified from two hospitals: St Bartholomew's Hospital and St Thomas' Hospital (UK)

When is the study starting and how long is it expected to run for?
June 2017 to September 2018

Who is funding the study?
Medical Research Council (UK)

Who is the main contact?
Professor David Wald

# Contact information

### Type(s)
Public

### Contact name
Prof David Wald

### Contact details
Wolfson Institute of Preventive Medicine
Charterhouse Square
London
United Kingdom
EC1M 6BQ

# Additional identifiers

### Clinical Trials Information System (CTIS)
2015-000704-25

### Protocol serial number
PAS01

# Study information

### Scientific Title
Prevention of Aortic Stenosis pilot trial: a randomised cross-over trial

### Acronym
PAS Pilot Trial

### Study objectives
The aim of this study is to assess the efficacy of sevelamer in lowering serum phosphate in patients with aortic stenosis.

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
Westminster Research Ethics Committee, 24/02/2017, ref: 17/LO/0120

### Study design
Randomised placebo-controlled double blind cross-over trial

### Primary study design
Interventional

### Study type(s)
Prevention

### Health condition(s) or problem(s) studied
Aortic stenosis

### Interventions
All participants in the study will have two periods taking sevelamer (a different dose in each period) and a period taking a placebo (a dummy pill), each period lasting six weeks (18 weeks overall). The sequence of treatments and placebo will be allocated at random. There are no off-treatment washout periods because the treatment period (6 weeks) is long enough for the effect of the previous treatment to have washed out by the end of each treatment period.

1. 800mg sevelamer three times a day (low dose)
2. 2.4g sevelamer three times a day (standard dose)
3. Placebo three times a day

### Intervention Type
Drug

### Phase
Phase II

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

### Primary outcome(s)
Serum phosphate, measured using standard methods for lab analysis at baseline, 6, 12 and 18 weeks

### Key secondary outcome(s))
Urine phosphate, measured using standard methods for lab analysis at 6, 12 and 18 weeks

### Completion date
15/09/2018

## Eligibility

### Key inclusion criteria
1. Aortic stenosis (Vmax 2.0-4.0 m/s)
2. Age 18-90

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Adult

### Lower age limit
18 years

### Upper age limit
90 years

### Sex
All

### Total final enrolment
72

### Key exclusion criteria
1. Contraindications, including a history of allergy to sevelamer, a history of hypophosphataemia or a history of bowel obstruction
2. A requirement for phosphate binding drugs for other reasons
3. A requirement for drugs that interact with phosphate binding drugs
4. A history of lactose intolerance
5. Any illness judged to contra-indicate participation in the trial
6. Pregnant or breastfeeding women

### Date of first enrolment
15/06/2017

### Date of final enrolment
15/06/2018

## Locations

### Countries of recruitment
United Kingdom

England

### Study participating centre
**Wolfson Institute of Preventive Medicine**
Charterhouse Square
London
United Kingdom
EC1M 6BQ

### Study participating centre

**St Bartholomew's Hospital**
West Smithfield
London
United Kingdom
EC1A 7BE

**Study participating centre**
**St Thomas' Hospital**
Westminster Bridge Road
Lambeth
London
United Kingdom
SE1 7EH

# Sponsor information

**Organisation**
Queen Mary University of London

**ROR**
https://ror.org/026zzn846

# Funder(s)

**Funder type**
Research council

**Funder Name**
Medical Research Council

**Alternative Name(s)**
Medical Research Council (United Kingdom), UK Medical Research Council, Medical Research Committee and Advisory Council, MRC

**Funding Body Type**
Government organisation

**Funding Body Subtype**
National government

**Location**
United Kingdom

# Results and Publications

## Individual participant data (IPD) sharing plan

Pseudoanonymised trial data stored in secure Safe Haven repository at Centre for Environmental and Preventive Medicine. Data requests to Prof. David Wald (custodian).

## IPD sharing plan summary

Stored in repository

## Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | results | 01/10/2019 | 12/09/2019 | Yes | No |
| HRA research summary | | | 28/06/2023 | No | No |