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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