ISRCTN15915491 https://doi.org/10.1186/ISRCTN15915491

Iloprost in patients with Eisenmenger syndrome

Submission date 04/02/2015	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 05/02/2015	**Overall study status** Completed	
Last Edited 20/05/2022	**Condition category** Circulatory System	

Plain English summary of protocol

Background and study aims
Eisenmenger's Syndrome is a congenital condition affecting the heart which results in low oxygen levels in the blood and high blood pressure within the lungs. The increase in blood pressure is caused by thickening and narrowing of the blood vessels in the lung. Currently, treatment includes relatively new medications called “advanced therapies”, which are “pulmonary vasodilators”; this means that they open up the blood vessels and help blood flow through the lungs and improve the function of the heart. These medications have been shown to improve patients’ symptoms and also length of life. These treatments are expensive and are tightly regulated. At present, the Commissioners allow us to treat patients with up to two types of pulmonary vasodilators; normally both tablets. A third class of medication are the “prostanoids”. These are unstable medicines which need to be given regularly, either as a nebuliser (inhaled) or intravenously. At present, although licensed for use in Eisenmenger syndrome, we are not allowed to prescribe such medicines on top of two tablets. This study aims to investigate whether iloprost, an inhaled prostanoid, is beneficial in terms of exercise capacity in patients who are deteriorating or have an unsatisfactory response to two oral therapies.

Who can participate?
Adults (aged at least 18) with Eisenmenger's Syndrome.

What does the study involve?
Participants are randomly allocated into one of two groups. Those in group 1 are given iloprost . Those in group 2 are given an inhaled placebo. Each participant receives one study drug for 12 weeks, have a 1 week “washout” and then take the other medication for a further 12 weeks, in a so called “crossover” study. At the end of the study all participants are able to take iloprost indefinitely in an “openlabel” phase. During the study, participant responses such as walking distance, oxygen levels, quality of life questionnaire and heart function as determined by ultrasound (echocardiography) are monitored.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
Royal Brompton Hospital (UK)

When is the study starting and how long is it expected to run for?
December 2014 to May 2016

Who is funding the study?
Bayer PLC (UK)

Who is the main contact?
Ms Natalie Dormand

Contact information

Type(s)
Scientific

Contact name
Ms Natalie Dormand

Contact details
Royal Brompton Hospital
Sydney Street
London
United Kingdom
SW3 6NP

Additional identifiers

EudraCT/CTIS number
2014-000091-25

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
18181

Study information

Scientific Title
A single-centre, placebo-controlled, double-blinded, randomized, crossover study of Iloprost (Ventavis®) in patients with Eisenmenger syndrome

Study objectives
This study aims to investigate whether iloprost, an inhaled prostanoid, is beneficial in terms of exercise capacity in Eisenmenger syndrome patients who are deteriorating or have an unsatisfactory response to two oral therapies.

Ethics approval required
Old ethics approval format

Ethics approval(s)
14/LO/1182

Study design
Randomised; Interventional; Design type: Treatment

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Topic: Cardiovascular disease; Subtopic: Cardiovascular (all Subtopics); Disease: Congenital Heart Disease and Pulmonary Hypertension

Interventions
Use of nebulised Iloprost in addition to maximum oral pulmonary vasodilative therapy.

The study will involve patients receiving either iloprost or an inhaled placebo; both doctors and patients will be “blinded” to what they are receiving. The patient will receive one study drug for 12 weeks, have a 1 week “washout” and then take the other medication for a further 12 weeks, in a socalled “crossover” study. At the end of the study the patient will be able to take iloprost indefinitely in an “openlabel” phase. During the study we will monitor responses such as walking distance, oxygen levels, quality of life questionnaire and heart function as determined by ultrasound (echocardiography).

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Iloprost

Primary outcome measure
Change in 6 Minute Walk Test over 3 months compared with placebo

Secondary outcome measures
N/A

Overall study start date
15/12/2014

Completion date
15/05/2016

Eligibility

Key inclusion criteria
1. Patients > 18 years
2. Body weight > 40 kg
3. Functional class III (1998 WHO classification)
4. Patients with documented oxygen saturation < 90%, at rest or during exercise with room air
5. Patients with established pulmonary hypertension related to congenital heart disease and post – tricuspid lesion able to perform a 6minute
walk test with latest walking distance < 400m or deterioration of 30m within 1 Year on dual oral therapy or patient not tolerating oral therapy
6. Patients stable for at least 3 months prior to screening
7. Patients providing written informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 15; UK Sample Size: 15

Key exclusion criteria
1. Pregnant patients
2. Trisomy 21
3. Obstructive lung disease (FEV1/FVC<60%)
4. Patients with systolic blood pressure <90 mm Hg
5. Patients with other conditions that may affect the ability to perform a six minute walk test
6. Patients unable to provide informed consent and comply with the protocol
7. Patients with known coronary artery disease
8. Patients who have started or stopped specific treatment for PAH within one month of screening, excluding anticoagulation
9. Patients active on an organ transplant list
10.Patients taking other investigational drugs/devices
11. Patients taking other Prostacyclin analogues, like Epoprostenol or Treprostinil
12. Patients with planned surgical intervention during the study period
13. Patients with HIV

Date of first enrolment
15/12/2014

Date of final enrolment
15/05/2016

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Royal Brompton Hospital
Sydney Street
London
United Kingdom
SW3 6NP

Sponsor information

Organisation
Royal Brompton & Harefield NHS Trust

Sponsor details
Royal Brompton Hospital
Sydney Street
London
England
United Kingdom
SW3 6NP

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/02218z997

Funder(s)

Funder type
Industry

Funder Name
Bayer PLC (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results		11/02/2021	20/05/2022	No	No
HRA research summary			26/07/2023	No	No