ISRCTN97515585 https://doi.org/10.1186/ISRCTN97515585

A randomised controlled trial of the effect of angiotensin-converting enzyme inhibitors on pulmonary regurgitation, biventricular volume, mass and function, integrated cardiopulmonary exercise and cardiac autonomic reflexes late after Tetralogy of Fallot repair. The APPROPRIATE study (Ace inhibitors for PRevention Of Pulmonary Regurgitation In Adults with TEtralogy)

Submission date
06/07/2005

Recruitment status
No longer recruiting

Registration date
08/08/2005

Overall study status
Completed

Last Edited
05/11/2010

Condition category
Circulatory System

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
BHF Project Grant PG/02/027

Study information

Scientific Title

Acronym
APPROPRIATE

Study objectives
Angiotensin-Converting Enzyme (ACE) inhibitor therapy reduces the degree of pulmonary regurgitation and improves right ventricular function, exercise capacity and baroreceptor sensitivity in patients with repaired Tetralogy of Fallot and pulmonary regurgitation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Repaired Tetralogy of Fallot

Interventions
Ramipril 10 mg once daily for six months compared to placebo (blister packaged capsules indistinguishable from the blister packaged active drug and also taken in increasing dose 2.5 mg for one week, then 5 mg for two weeks then 10 mg for rest of study).

All patients have two safety blood tests on the basis that they may be on ramipril. There is a protocol of openly changing to losartan in the circumstance of intractable cough. The trial is double blinded and all investigators remain blind as the study is ongoing.

Intervention Type
Drug

Phase
Not Specified

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

Primary outcome measure
Improvement in right ventricular function

Secondary outcome measures
1. Reduction in pulmonary regurgitant fraction
2. Reduction of right ventricular volume
3. Reduction of right ventricular mass
4. Reduction of left ventricular volume
5. Improvement of left ventricular systolic function
6. Improvement of exercise performance
7. Improvement in baroreceptor sensitivity and heart rate variability

Overall study start date
01/10/2002

Completion date
14/07/2005

Eligibility

Key inclusion criteria
All patients with repaired Tetralogy of Fallot and moderate or more pulmonary regurgitant fraction.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
25-30 in each arm

Key exclusion criteria
1. Known allergy or hypersensitivity to ACE-inhibitors
2. History of coronary artery disease
3. Pulmonary stenosis more than mild
4. Unable to undertake Cardiovascular Magnetic Resonance (permanent pacemaker, electrical device etc.)
5. Renal failure, assessed from patients clinical notes and baseline biochemistry check.
6. Ongoing ACE-inhibitor therapy
7. Pregnancy/breastfeeding/planning to conceive during participation
8. Systolic blood pressure less than 90 mmHg
9. Hyperkaliemia (K+ levels more than 5.5 mEq/l)
10. Refusal to give informed consent

Date of first enrolment
01/10/2002

Date of final enrolment
14/07/2005

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Adult Congenital Heart Unit
London
United Kingdom
SW3 6NP

Sponsor information

Organisation
British Heart Foundation (UK)

Sponsor details

14 Fitzhardinge Street
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W1H 6DH
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Sponsor type
Charity

Website
http://www.bhf.org.uk

ROR
https://ror.org/02wdwnk04

Funder(s)

Funder type
Charity

Funder Name
British Heart Foundation

Alternative Name(s)
the_bhf, The British Heart Foundation, BHF

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Funder Name
Project Grant PG/02/027

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?
Results article	results	09/02/2012		Yes	No