

# The development and feasibility of an intervention to reassure patients about test results in rapid access chest pain clinic

<b>Submission date</b> 27/05/2011	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 27/05/2011	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 06/10/2014	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Prof Gill Furze

**Contact details**  
Coventry University  
Room 309, Richard Crossman Building  
Priory Street  
Coventry  
United Kingdom  
CV1 5FB

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
9810

# Study information

## Scientific Title

The development and feasibility of an intervention to reassure patients about test results in a rapid access chest pain clinic

## Study objectives

The study has two parts:

1. In the first part (the development phase), an intervention will be developed with input from experts, patients and clinic staff. The intervention will be a brief (10 - 15 mins) face-to-face discussion delivered by a nurse to patients attending rapid access chest pain clinic (RACPC) that will explain to the patients the tests they are going to undergo in RACPC, the possible test results they may get, and what the possible treatments may be for the different test results. This discussion will take place before the patients undergo their test in RACPC and the aim of the intervention is to increase patients reassurance with their test results and ensuing treatment. A focus group of ten previous RACPC patients will be setup to gain their views on the draft intervention. The final draft intervention will be tested in ten patients in RACPC before being finalised.

2. (The pilot trial phase) we will undertake a pilot randomised controlled trial (RCT) with 120 patients in RACPC. The two-arm study will compare the intervention (face-to-face discussion developed in the first part of the study) PLUS usual care (a written leaflet giving the same information - tests that may be undertaken in RACPC, results and potential ensuing treatments) VERSUS usual care alone. The pilot RCT will inform the design of a future multicentre trial.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

First MREC approval date 15/12/2010, ref: 10/H1014/82

## Study design

Randomised, interventional, observational qualitative trial

## 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 the contact details below to request a patient information sheet

**Health condition(s) or problem(s) studied**

Cardiovascular disease

**Interventions**

1. Nurse-facilitated intervention: a brief (10 - 15 mins) face-to-face discussion delivered by a nurse to patients attending rapid access chest pain clinic (RACPC) that will explain to the patients the tests they are going to undergo in RACPC, the possible test results they may get, and what the possible treatments may be.
2. Follow up length: 6 month(s)
3. Study entry: single randomisation only

In the first stage of the study, ten participants will be recruited for the focus group and ten participants will be recruited for testing each draft of the intervention. For the pilot RCT, we propose to recruit 120 participants (60 per group).

**Intervention Type**

Other

**Phase**

Not Applicable

**Primary outcome measure**

1. Patient reported reassurance
2. Timepoint(s): 1 month and six months

**Secondary outcome measures**

No secondary outcome measures

**Overall study start date**

30/03/2011

**Completion date**

30/06/2012

**Eligibility****Key inclusion criteria**

Applies to the developmental phase and the pilot study:

1. All patients attending RACPC for assessment of new-onset, non-urgent chest pain
2. Able to read written English
3. Able to comprehend spoken English
4. Aged 18 years and over
5. Able and willing to give informed consent
6. Target gender: male & female
7. Lower age limit 18 years

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

Planned Sample Size: 140; UK Sample Size: 140;

**Key exclusion criteria**

Pilot study only:

1. Previously diagnosed cardiac pathology
2. No symptoms of chest pain
3. Undertaking the stress test as part of a pre-surgical medical examination
4. Pregnant
5. Currently involved in a research study
6. Severe documented psychiatric disorder (psychosis/bipolar disorder)
7. Life threatening co-morbidities

**Date of first enrolment**

30/03/2011

**Date of final enrolment**

30/06/2012

## **Locations**

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

**Coventry University**

Coventry

United Kingdom

CV1 5FB

## **Sponsor information**

**Organisation**

University of York (UK)

### Sponsor details

Department of Health Sciences  
York Trials Unit  
Area 4  
Sebohm Rowntree Building  
Heslington  
York  
England  
United Kingdom  
YO10 5DD

### Sponsor type

University/education

### Website

<http://www.york.ac.uk/>

### ROR

<https://ror.org/04m01e293>

## Funder(s)

### Funder type

Government

### Funder Name

NIHR Research for Patient Benefit Programme (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="#">Results article</a>	results	04/10/2014		Yes	No