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Positron Emission Tomography And Recovery following Revascularization: Outcomes and Cost-Effectiveness using F-18-fluorodeoxyglucose (FDG) PET in Severe Left Ventricular Dysfunction (PARR Phase 2)

Submission date 22/10/2007	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol
Registration date 22/10/2007	**Overall study status** Completed	[_] Statistical analysis plan [X] Results
Last Edited 01/04/2010	**Condition category** Circulatory System	[_] 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

ClinicalTrials.gov (NCT)

NCT00385242

Protocol serial number
MCT-37412

Study information

Scientific Title
Positron Emission Tomography And Recovery following Revascularization: A Multi Centre, Randomized Trial of Evaluation of Outcome and Cost-Effectiveness using an F-18-fluorodeoxyglucose (FDG) PET-Guided Approach to Management of Patients with Coronary Disease and Severe LV Dysfunction (PARR Phase 2)

Acronym
PARR 2

Study objectives
1. Therapy guided by by F-18-fluorodeoxyglucose (FDG) Positron Emission Tomography (PET) imaging achieves a better long-term (5-year) clinical outcome than an approach without PET available ('standard care') for patients with severe LV dysfunction
2. A PET-guided approach to therapy is economically attractive in patients with severe LV dysfunction - determine costs
3. Therapy guided by FDG PET leads to better LV function and quality of life than standard care, in patients with severe LV dysfunction, after long-term follow-up

As of 2007, a follow-up study has been approved for funding by the Canadian Institutes of Health Research (CIHR), with the same CIHR grant reference, and with added outcomes. This follow-up study is entitled: 'PET and Recovery following Revascularization (PARR 2) extended follow-up', and all information specifically pertaining to this extended follow-up will be noted under this title.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Human Research Ethics Committee of the University of Ottawa Heart Institute, Ottawa, Ontario (Canada) approved on the 11th February 1999 (ref: #UOHI-98-148).

Ethics approval for the PET and Recovery following Revascularization (PARR 2) extended follow-up received from the Human Research Ethics Board of the University of Ottawa Heart Institute, Ottawa, Ontario (Canada) on the 29th January 2007 (ref: #UOHI-1998-148).

Primary study design
Interventional

Study design
Multicentre two arm randomized parallel trial on diagnostic strategy

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Coronary artery disease, LV dysfunction, congestive heart failure

Interventions
1. FDG PET-guided therapy group:
Patients randomized to this group underwent perfusion and FDG PET imaging within 2 weeks of randomization. When FDG PET identified significant viable myocardium the PET-guided therapy arm recommended:
1.1. Revascularization (Coronary Artery Bypass Graft [CABG] or Percutaneous Transluminal Coronary Angioplasty [PTCA]) within 6 weeks if the patient had had angiography, or
1.2. Revascularization work-up if the patient had not had recent angiography

When PET did not identify any significant viable myocardium (i.e. predominantly PET scar), the PET-guided therapy arm would recommend no revascularization. The attending physicians were asked to follow the directive of the PET-guided therapy. Patients who did not have a PET scan or had an event before receiving a PET scan were considered as crossovers.

2. Control group:
The standard care arm proceeded without PET available. An alternative test for viability could be considered at the physician's discretion. If the clinical status of an enrolled patient changed such that the attending physician would not proceed without PET data, the patient was considered as a crossover.

The contact for public and scientific queries for both the original trial and the extended follow-up is Dr Rob Beanlands (contact details can be found below).

Please note that the actual start and end dates of the original trial were:
Start date: 31/05/2000
End date: 24/06/2004

PET and Recovery following Revascularization (PARR 2) extended follow-up:
This extended follow-up has the following start and end dates:
Actual start date: 31/05/2000
Anticipated end date: 01/09/2009

As of 08/05/2009 this record was updated to reflect the details of a new sponsor; the initial sponsor at the time of registration was University of Ottawa (Canada).

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
The occurrence of the composite clinical end point of cardiac death, myocardial infarction, cardiac arrest, transplantation, or re-hospitalization for unstable angina or heart failure (at 1 year).

PET and Recovery following Revascularization (PARR 2) extended follow-up:
The same outcomes as above, measured at 5 years.

Key secondary outcome(s)
Measured at 1 year:
1. Time to occurrence of the composite endpoint
2. Individual components of the composite endpoint
3. Ejection fraction
4. Quality of life
5. Cost and cost-effectiveness of PET-guided therapy versus control

PET and Recovery following Revascularization (PARR 2) extended follow-up:
Measured every six months up to 5 years:
1. Time to occurrence of the composite endpoint
2. Individual components of the composite endpoint
3. Ejection fraction
4. Quality of life

Completion date
30/06/2004

Eligibility

Key inclusion criteria
1. Age greater than or equal to 18 years, either sex
2. Coronary artery disease documented by coronary angiography, previous myocardial infarction (MI), previous revascularization procedure or positive exercise stress/perfusion imaging
3. Severely reduced LV function with ejection fraction (EF) less than or equal to 35% attributable to coronary disease
4. Any patient being considered for revascularization, transplant/heart failure work up or where in the opinion of the attending physician viability imaging would be considered useful in the ongoing clinical managements

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Co-morbid medical conditions likely to make survival for the duration of the study unlikely
2. Less than four weeks post MI

3. Not suitable for revascularization before randomization
4. Patients requiring emergency revascularization
5. Lack of informed consent

Date of first enrolment
01/05/2000

Date of final enrolment
30/06/2004

Locations

Countries of recruitment
Canada

Study participating centre
University of Ottawa Heart Institute
Ontario
Canada
K1Y 4W7

Sponsor information

Organisation
University of Ottawa Heart Institute (Canada)

ROR
https://ror.org/03c4mmv16

Funder(s)

Funder type
Research organisation

Funder Name
Canadian Institutes of Health Research (CIHR) (Canada) - http://www.cihr.irsc.gc.ca (ref: MCT-37412)

Funder Name
Heart and Stroke Foundation (Canada)

Funder Name
MDS Nordion (Canada)

Results and Publications

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	01/09/2009		Yes	No
Results article	results	01/04/2010		Yes	No
Protocol article	protocol	01/12/2003		Yes	No