An evaluation of the clinical and costeffectiveness of pulmonary artery flotation catheters (PAC-Man) in intensive care.

Submission date	Recruitment status No longer recruiting	Prospectively registered		
25/04/2003		☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
25/04/2003	Completed	[X] Results		
Last Edited 03/09/2009	Condition category Circulatory System	[] Individual participant data		

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

Study information

Scientific Title

Acronym

PAC-Man

Study objectives

The primary hypothesis is: there is no significant difference in hospital mortality or costs of care for those critically ill patients in adult ICUs who receive PAFC and those who do not.

The secondary hypotheses are: there is no significant difference in hospital mortality or costs of care for those high risk critically ill patients in adult ICUs who receive PAFC and those who do not - where high risk is defined as patients with a hospital mortality risk of 50% or greater; there is no significant difference in hospital mortality or costs of care, by "skill of use", for those critically ill patients in adult ICUs who receive PAFC and those who do not where "skill of use" will encompass insertion technique, interpretation of data from PAFC and subsequent management decisions.

Design (i): Systematic review - the systematic review is to inform important methodological criteria for the final design of the subsequent RCT:

- 1. Evidence of the clinical and cost-effectiveness of PAFC (to help finalise the design of the RCT) 2 Evidence on the indications for PAFC (to help finalise any exclusion criteria and to help inform the risk stratification criteria for the RCT)
- 3. Evidence of complications following insertion of PAFC (to help inform the "skill of use" stratification and outcome measurement in RCT)
- 4. Evidence of interpretation/misinterpretation of data from PAFC (to help inform the "skill of use" stratification or the RCT)
- 5. Evidence on management decisions arising from interpretation of data from PAFC (to help inform the "skill of use" stratification for the RCT).

Design (ii): Randomised controlled trial - The proposed RCT will have one primary and two secondary objectives:

- 1. To evaluate the clinical and cost-effectiveness of PAFC in intensive care patients, including high risk surgical patients, as currently used in the NHS
- 2. To evaluate the clinical and cost-effectiveness of PAFC in high risk patients
- 3. To evaluate the clinical and cost-effectiveness of PAFC "skill of use".

Setting: Adult general ICUs in the UK

Health Technologies Being Assessed: PAFC, as per objectives.

Project Timetable: Months 1-12: Systematic review/preparation for RCT/ethical approval Months 13-24: Recruitment/data validation/follow-up

Months 25-36: Follow-up/data analysis/writing up/dissemination

Sample Size: The most recent and most generalisable information available for sample size calculation derive from adult, general intensive care unit in Scotland in 1995/6. This indicated that 19% of patients received PAFC and that hospital mortality in this group was 52% as compared with 23% for patients without PAFC. To answer the hypotheses with sufficient power (90% power, p<0.05) and assuming 90% compliance, an estimate of X patients per group is required.

Recruitment Rate: It is hoped that most ICUs (n=132) participating in the national, comparative audit of patient outcome, co-ordinated by ICNARC (over 50% in England and Wales), will

participate in the RCT. Average annual throughput in an average sized intensive care unit is 300 admissions per year of which 57 (19%) are estimated to receive PAFC, 6954 admissions annually in recruited units to the national audit.

Evaluation of risk adjustment: Due to the ethical problems of randomising patients to intensive care or not, the evaluation of the "package" of care is reliant on methods of risk adjustment. Five such methods are employed as part of the Case Mix Programme. The ability of these methods to mirror the results of the proposed RCT will be evaluated. The risk adjustment analysis will be performed by individuals masked to the results of the RCT. Such methodological work will inform us of our ability to risk adjust for hospital mortality following intensive care and establish the contribution that high quality clinical databases might make to health technology assessment.

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

Heart disease

Interventions

Patients in adult ICUs who are managed using PAC vs those who are not.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Hospital mortality, defined as death before discharge from hospital, incorporating death before discharge from ICU. There are no secondary outcome measures unless otherwise indicated by results of the systematic review.

Economic Evaluation: The costs of care will be estimated using a top-down method. Cost-effectiveness ratios will be estimated for each outcome. Appropriate incremental cost-effectiveness ratios will also be calculated and sensitivity analysis around the cost and outcome of care will be undertaken.

Secondary outcome measures

Not provided at time of registration.

Overall study start date

01/01/2000

Completion date

30/09/2004

Eligibility

Key inclusion criteria

All intensive care admissions, including high risk surgical patients.

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

1,041

Key exclusion criteria

Not provided at time of registration.

Date of first enrolment

01/01/2000

Date of final enrolment

30/09/2004

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Intensive Care National Audit & Research Centre

London United Kingdom WC1H 9HR

Sponsor information

Organisation

Department of Health (UK)

Sponsor details

Quarry House Quarry Hill Leeds United Kingdom LS2 7UE +44 (0)1132 545 843 Sheila.Greener@doh.gsi.gov.uk

Sponsor type

Government

Website

http://www.dh.gov.uk/en/index.htm

ROR

https://ror.org/03sbpja79

Funder(s)

Funder type

Government

Funder Name

NIHR Health Technology Assessment Programme - HTA (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?
Results article	results	01/08/2005		Yes	No