

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

Submission date 25/04/2003	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 25/04/2003	Overall study status Completed	☐ Statistical analysis plan ☒ 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

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Additional identifiers

Protocol serial number

HTA 97/08/03

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.

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

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(s)

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.

Key secondary outcome(s)

Not provided at time of registration.

Completion date

30/09/2004

Eligibility

Key inclusion criteria

All intensive care admissions, including high risk surgical patients.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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**

United Kingdom

England

Study participating centre

Intensive Care National Audit & Research Centre

London

United Kingdom

WC1H 9HR

Sponsor information**Organisation**

Department of Health (UK)

ROR

<https://ror.org/03sbpja79>

Funder(s)

Funder type

Government

Funder Name

NIHR Health Technology Assessment Programme - HTA (UK)

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	01/08/2005		Yes	No