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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 [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 25/04/2003	**Overall study status** Completed	
Last Edited 03/09/2009	**Condition category** Circulatory System	

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

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.

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

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Sponsor information

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Sponsor type
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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