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Multi-centre randomised controlled trial of nurse practitioners and pre-registration house officers (PRHO) in pre-operative workup

Submission date
25/04/2003

Recruitment status
No longer recruiting

Registration date
25/04/2003

Overall study status
Completed

Last Edited
11/03/2009

Condition category
Surgery

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
HTA 94/40/38

Study information

Scientific Title

Study objectives
To determine whether pre-operative assessment carried out by an appropriately trained nurse (ATN) is equivalent in quality to that carried out by a pre-registration house officer (PRHO).
To assess whether pre-assessments carried out by ATNs and PRHOs are equivalent in terms of cost.
To determine whether assessments carried out by ATNs are acceptable to patients.
To investigate the quality of communication between senior medical staff and ATNs.

More details can be found at: http://www.hta.ac.uk/993

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration.

Study design
Prospective randomised equivalence trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

Participant information sheet

Health condition(s) or problem(s) studied
Pre-operative assessment

Interventions
The study design was principally a prospective randomised equivalence trial but was accompanied by additional qualitative assessment of patient and staff perceptions, and an economic evaluation.
The intervention consisted of a pre-operative assessment carried out by either an appropriately trained nurse (ATN) or a PRHO. Of the patients who completed the study with a full evaluation,

926 patients were randomised to the PRHO arm of the trial and 948 to the ATN arm. Three ATNs took part in the study, one from each centre, together with a total of 87 PRHOs.

Intervention Type
Procedure/Surgery

Phase
Not Specified

Primary outcome measure
Immediately following the initial assessment of a patient by a PRHO or an ATN, one of a number of clinical research fellows, all specialist registrars in anaesthetics, repeated the assessment and recorded it on a study form, together with a list of investigations required. The clinical research fellow then evaluated the competency of the initial assessor by comparing the quality of their assessment with their own. Any deficiencies in ordering of investigations and referral to other specialities were met in order to maximise patient care. Three areas of ATN and PRHO performance were judged separately, history taking, examination and ordering of tests, and each was graded into one of four categories, the most important of which was under-assessment, which would possibly have affected peri-operative management. In the case of ordering of tests, it was possible to have both over- and under-assessed a patient on different tests.

Secondary outcome measures
Not provided at time of registration.

Overall study start date
01/10/1997

Completion date
31/10/1999

Eligibility

Key inclusion criteria
All patients attending at one site for assessment prior to general anaesthetic for elective general, vascular, urological or breast surgery were potentially included in the study. Of 1,907 patients who were randomised, 1874 completed the study with a full evaluation.

Participant type(s)
Patient

Age group
Not Specified

Sex
Both

Target number of participants
1,907

Key exclusion criteria
Not provided at time of registration.

Date of first enrolment
01/10/1997

Date of final enrolment
31/10/1999

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University Surgical Unit
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Sponsor information

Organisation
Department of Health (UK)

Sponsor details
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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	07/12/2002		Yes	No