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A pragmatic multi-centre randomised controlled evaluation of level of dependency and pre-operative fluid loading in high-risk surgical patients undergoing major elective and urgent surgery

Submission date 02/07/2007	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol
Registration date 30/08/2007	**Overall study status** Completed	[_] Statistical analysis plan [X] Results
Last Edited 01/07/2013	**Condition category** Surgery	[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Study website
https://www.charttrials.abdn.ac.uk/foccus/

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Acronym
FOCCUS

Study objectives
Whether:
1. Ward-based pre-operative fluid loading, and/or
2. Routine post-operative care in an Intensive Care Unit (ICU),
improve outcome in high-risk surgical patients undergoing major elective and urgent surgery, and are effective and cost-effective.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the Multi Centre Research Ethics Committee for Scotland on the 21st March 2005 (ref: 04/MRE10/76). On 10th April 2007 the Committee Co-ordinator confirmed that the start date of 17th August 2007 is acceptable.

Study design
Multicentre, prospective, randomised, controlled trial with a partial 2 x 2 factorial design. The term partial recognises that some patients might not be recruited to the HDU versus ICU comparison.

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Abdominal and thoraco-abdominal surgery

Interventions
Initial randomisation is to pre-operative fluid therapy or standard regimen:
1. Pre-operative fluid therapy - patients will be electively commenced on pre-operative fluid therapy (25 ml/kg) using Hartmanns solution over six hours before surgery in the ward
2. Standard fluid regimen - No routine pre-operative fluid therapy

The second randomisation is to routine ICU or High Dependency Unit (HDU) for post-operative care:
1. ICU care - Initial post-operative care undertaken in the ICU under the care of ICU clinicians
2. HDU care - Initial post-operative care undertaken in a surgical HDU under the care of the surgical team
Due to a possible lack of availability of ICU beds, we anticipate randomising approximately 174 of the participants to the second stage.

The expectation is that trial participants will remain in ICU or HDU according to their allocation for at least 48 hours after surgery unless a clear clinical reason for a change develops. All participants will be followed up for one week for major morbidity and mortality, then at one, three and six months after surgery for survival and quality of life.

Intervention Type
Procedure/Surgery

Phase
Not Specified

Primary outcome measure
1. For the comparison of level of care (ICU versus HDU): cost-effectiveness at six months, measured by participant completed questionnaires and primary and secondary care costs
2. For the comparison of fluid optimisation: number of hospital days after surgery

Secondary outcome measures
1. Health status at one month after surgery measured using participant completed survey
2. Quality of life at 48 hours, three and six months after surgery measured using participant completed surgery
3. Changes in health status and quality of life six months after surgery
4. Health care costs, including full hospital costs and primary care costs, in the six months post surgery
5. Mortality and morbidity - mortality using time-to-event analysis
6. Incidence of major morbidities in hospital using Post-Operative Morbidity Score

Overall study start date
17/08/2007

Completion date
16/07/2009

Eligibility

Key inclusion criteria
1. Undergoing major elective and urgent abdominal and thoraco-abdominal surgery
2. Fulfil high-risk surgical criteria
3. Have signed informed consent

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
204 participants to the first randomisation comparing fluid optimisation.

Key exclusion criteria
1. New York Heart Association grade IV heart failure
2. Clinician concern
3. Emergency surgery
4. Chronic renal failure/creatinine greater than 200 umol/L
5. Lack of informed consent
6. Aged less than 16 years
7. Pregnancy
8. Major hepatic surgery, expected survival less than six months

Date of first enrolment
17/08/2007

Date of final enrolment
16/07/2009

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre
3rd Floor
Aberdeen
United Kingdom
AB25 2ZD

Sponsor information

Organisation
University of Aberdeen (UK)

Sponsor details
University Office
Kings College
Aberdeen
Scotland
United Kingdom
AB24 3FX

Sponsor type
University/education

Website
http://www.abdn.ac.uk/R&I

ROR
https://ror.org/016476m91

Funder(s)

Funder type
Government

Funder Name
Chief Scientist Office of the Scottish Executive Health Department (UK) (ref: CZH/4/392)

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?

Protocol article	protocol	16/04/2010	Yes	No
Results article	results	01/04/2011	Yes	No