

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	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 30/08/2007	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 01/07/2013	Condition category Surgery	<input type="checkbox"/> 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
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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

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

United Kingdom

Scotland

Study participating centre

3rd Floor

Aberdeen

United Kingdom

AB25 2ZD

Sponsor information

Organisation

University of Aberdeen (UK)

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

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	01/04/2011		Yes	No
Protocol article	protocol	16/04/2010		Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes