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A pilot randomised controlled trial of systemic warming during the initial hospital phase of elderly fallers and patients with abdominal pain or suspected fractured neck of femur

Submission date
29/09/2006

Recruitment status
No longer recruiting

Registration date
29/09/2006

Overall study status
Completed

Last Edited
23/05/2012

Condition category
Injury, Occupational Diseases, Poisoning

[_] 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

Contact name
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Contact details
C/o Dr EA Baker, Professorial Unit of Surgery
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United Kingdom
TS19 8PE

Additional identifiers

Protocol serial number
N0159166708

Study information

Scientific Title

Study objectives
The proposed study aims to investigate the value of warming during the initial hospital phase of three groups of patients (A&E patients, elderly fallers and those with abdominal pain or suspected fractured neck of femur). The warming will take place from the time of admission for 4 hours or until discharge whichever comes first. We will use clinical variables to assess various clinical outcomes.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Pilot randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Injury, Occupational Diseases, Poisoning: Fractured neck of femur

Interventions
Avoidance of hypothermia in the peri-operative period has convincingly shown to reduce mortality and morbidity especially infectious complications. In this proposed randomised controlled trial, patients will be randomised into two groups on admission:
1. The intervention group will receive systematic warming.
2. The control group will not receive warming but will receive standard care currently provided by the hospital.

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
1. Core temperature on leaving the A&E / post warming
2. Pain scores on leaving A&E / post warming
3. Thermal comfort scores on leaving A&E / post warming

Key secondary outcome(s))
Not provided at time of registration

Completion date
30/09/2007

Eligibility

Key inclusion criteria
150 patients in total, 50 for each group from:
1. Adult patients presenting to A&E/Emergency Assessment Unit
2. Elderly fallers (over 65 yrs)
3. Adults with abdominal pain or suspected fractured neck of femur

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Not Specified

Sex
Not Specified

Key exclusion criteria
1. Patients with suspected acute coronary syndromes or in cardiac arrest
2. Patients who would normally be transported on a spine board
3. Patients suffering from dementia
4. Patients with pyrexia (>39 degree Celsius).

Date of first enrolment
23/05/2005

Date of final enrolment
30/09/2007

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
C/o Dr EA Baker, Professorial Unit of Surgery
Stockton-on-Tees
United Kingdom
TS19 8PE

Sponsor information

Organisation
Record Provided by the NHSTCT Register - 2006 Update - Department of Health

Funder(s)

Funder type
Government

Funder Name
North Tees and Hartlepool NHS Trust (UK), NHS R&D Support Funding

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	01/04/2007		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes