

# 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

Prospectively registered

Protocol

**Registration date**

29/09/2006

**Overall study status**

Completed

Statistical analysis plan

Results

**Last Edited**

23/05/2012

**Condition category**

Injury, Occupational Diseases, Poisoning

Individual participant data

**Plain English summary of protocol**

Not provided at time of registration

## Contact information

**Type(s)**

Scientific

**Contact name**

Prof David J Leaper

**Contact details**

C/o Dr EA Baker, Professorial Unit of Surgery

University Hospital of North Tees

Stockton-on-Tees

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?
<a href="#">Results article</a>	results	01/04/2007		Yes	No