

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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

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 measure

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

Secondary outcome measures

Not provided at time of registration

Overall study start date

23/05/2005

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

Age group

Not Specified

Sex

Not Specified

Target number of participants

150

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

England

United Kingdom

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

Sponsor details

The Department of Health, Richmond House, 79 Whitehall

London

United Kingdom

SW1A 2NL

+44 (0)20 7307 2622

dhmail@doh.gsi.org.uk

Sponsor type

Government

Website

<http://www.dh.gov.uk/Home/fs/en>

Funder(s)

Funder type

Government

Funder Name

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

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	01/04/2007		Yes	No