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A randomised controlled trial of infusion protocols in adult pre-hospital care

Submission date	Recruitment status
25/04/2003	No longer recruiting
Registration date	**Overall study status**
25/04/2003	Completed
Last Edited	**Condition category**
07/04/2020	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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
HTA 93/23/19

Study information

Scientific Title
A randomised controlled trial of infusion protocols in adult pre-hospital care

Study objectives
The initiation of intravenous fluid replacement in injured patients at the accident scene is becoming a routine procedure. It has been assumed that early volume replacement in a bleeding patient will result in the patient arriving at hospital in a better haemodynamic state than if no fluids are given. However, some non-randomised studies of trauma patients and one quasi-randomised study of patients with severe bleeding injuries have begun to cast doubt on this assumption.
In the UK most on-scene fluid therapy is given by ambulance-service paramedics acting in accordance with their protocols. We therefore conducted a pragmatic study to compare the effects of two different fluid protocols, one usually with fluid administration and one usually without, used by paramedics.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approval from 16 local research ethics committees

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

Participant information sheet

Health condition(s) or problem(s) studied
Injury, occupational diseases, poisoning: Other injury, occupational diseases, poisoning

Interventions
With approval from 16 local research ethics committees, paramedics in two ambulance services were randomly allocated to one of two treatment protocols for the prehospital use of intravenous fluids in adult trauma patients. Paramedics who had been qualified for at least 1 year were randomised to an initial treatment protocol using a simple random-number generator. Approximately half way through the trial the paramedics were crossed over to the alternative protocol. Cluster randomised controlled. trial.

Protocol A: intravenous fluids were administered at the incident scene to all adult trauma patients who under current procedures the paramedic would consider starting on intravenous fluids.
Protocol B: fluids were withheld until arrival at hospital, unless the time to hospital was likely to be over 1 hour.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Death, complications, general health status (measured using the Short Form with 36 items (SF-36) questionnaire), processes of care and costs were measured up to 6 months post-incident.

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/12/1995

Completion date
31/01/1998

Eligibility

Key inclusion criteria
Trauma patients aged 16 years or over who died or stayed in hospital for three or more nights and who were attended by a paramedic crew randomised to a treatment protocol were included in the study.

Participant type(s)
Patient

Age group
Adult

Sex
Not Specified

Target number of participants
1309

Total final enrolment
1309

Key exclusion criteria
Patients with burns, poisoning, asphyxiation, minor uncomplicated skin or skeletal injuries, isolated fractured neck of femur, or who were pregnant were excluded.

Date of first enrolment
01/12/1995

Date of final enrolment
31/01/1998

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
School of Health and Related Research
Sheffield
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Sponsor information

Organisation
Department of Health (UK)

Sponsor details
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Sponsor type
Government

Website
http://www.dh.gov.uk/en/index.htm

ROR
https://ror.org/03sbpja79

Funder(s)

Funder type
Government

Funder Name
NIHR Health Technology Assessment Programme - HTA (UK)

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	01/12/2000		Yes	No