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

Submission date	Recruitment status  No longer recruiting	Prospectively registered	
25/04/2003		☐ Protocol	
Registration date 25/04/2003	Overall study status Completed	Statistical analysis plan	
		[X] Results	
<b>Last Edited</b> 07/04/2020	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 John Nicholl

#### Contact details

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# Additional identifiers

Protocol serial number 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

# Study type(s)

**Not Specified** 

# 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(s)

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.

### Key secondary outcome(s))

Not provided at time of registration

#### 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** 

# Healthy volunteers allowed

No

#### Age group

Adult

#### Sex

**Not Specified** 

#### 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

**United Kingdom** 

England

Study participating centre School of Health and Related Research Sheffield United Kingdom S1 4DA

# Sponsor information

## Organisation

Department of Health (UK)

#### **ROR**

https://ror.org/03sbpja79

# Funder(s)

# Funder type

Government

#### **Funder Name**

NIHR Health Technology Assessment Programme - HTA (UK)

# **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	01/12/2000		Yes	No