

The effects of 1L infusions of 0.9% saline and Voluven® on plasma volume, serum biochemistry and sodium and water controlling hormones in healthy volunteers: a double blind, randomised crossover study

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 28/09/2011	Condition category Other	☐ 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

Protocol serial number
N0192165308

Study information

Scientific Title

Study objectives

To study the responses of normal volunteers to 1 litre infusions of 0.9% saline and Voluven® over 1 hour. In particular the extent and time course of the effects of the two infusions on haematocrit, serum albumen, serum biochemistry, plasma expanding capacity and the resultant urinary responses will be measured.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Primary study design

Interventional

Study design

Double blind, randomised crossover study

Study type(s)

Not Specified

Health condition(s) or problem(s) studied

Effects of Voluven® infusion on plasma volume, serum biochemistry and sodium and water controlling hormones

Interventions

Double blind, randomised crossover study

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

saline and Voluven®

Primary outcome(s)

Difference in effects produced by the two infusions on haematocrit, serum albumin, chloride, osmolality, AVP, renin, ANP and aldosterone. Differences between the infusions will be tested for statistical significance using the Wilcoxon signed ranks test and repeated measures ANOVA. Differences will be considered significant if $P < 0.05$.

Key secondary outcome(s)

Not provided at time of registration

Completion date

27/03/2006

Eligibility

Key inclusion criteria

Male subjects aged between 18 and 40 years responding to local advertisement will be screened by questionnaire and medical examination before being chosen.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

Male

Key exclusion criteria

Subjects weighing less than 65kg or more than 80kg, those with medical conditions or allergies, those on regular medications, and participants in a study less than three months before will be excluded.

Date of first enrolment

27/06/2005

Date of final enrolment

27/03/2006

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

University Department of Anaesthesia

Nottingham

United Kingdom

NG7 2UH

Sponsor information

Organisation

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

Funder(s)

Funder type

Government

Funder Name

Queen's Medical Centre University Hospital NHS Trust (UK)

Funder Name

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	01/02/2010		Yes	No