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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 [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 29/09/2006	**Overall study status** Completed	
Last Edited 28/09/2011	**Condition category** Other	

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
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

Study design
Double blind, randomised crossover study

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
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 measure
Difference in effects produced by the two infusions on haemotocrit, serum albumin, chloride, osmolality, AVP, renin, ANP and aldosterone. Differences betwen 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.

Secondary outcome measures
Not provided at time of registration

Overall study start date
27/06/2005

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

Age group
Adult

Lower age limit
18 Years

Sex
Male

Target number of participants
10

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
England

United Kingdom

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

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

Funder Name
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	01/02/2010		Yes	No