Does the use of a simple portable ultrasound machine increase the success rate for femoral venous access in children and decrease complications?

Submission date 30/09/2004	Recruitment status No longer recruiting	Prospectively registeredProtocol
Registration date 30/09/2004	Overall study status Completed	Statistical analysis planResults
Last Edited 29/04/2016	Condition category Surgery	 Individual participant data Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s) Scientific

Contact name Dr Steven Cray

Contact details

Birmingham Children's Hospital Department of Anaesthesia Steelhouse Lane Birmingham United Kingdom B4 6NH +44 (0)121 333 9623 steven.cray@bch.nhs.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers N0045126775

Study information

Scientific Title

Does the use of a simple portable ultrasound machine increase the success rate for femoral venous access in children and decrease complications?

Study objectives

Does the use of a simple portable ultrasound machine increase the success rate for femoral venous access in children and decrease complications?

Ethics approval required Old ethics approval format

Ethics approval(s) Not provided at time of registration

Study design 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

Cardiac catheterisation

Interventions

Children undergoing cardiac catheterisation under general anaesthesia who require femoral venous access for that procedure will be randomised to either femoral venous access under ultrasound guidance or by the landmark method (palpation of the femoral artery). Children who are known to have thrombosed or abnormal venous anatomy will be excluded because these children will require specialised techniques of vascular access. A history of latex allergy will also be an exclusion criterion. The femoral venous puncture will be performed by a cardiologist trained in both techniques.

Intervention Type

Procedure/Surgery

Phase Not Specified

Primary outcome measure

The number of attempts to successful venous access, time taken and complications (arterial puncture, failure, haematoma) will be recorded. If after 15 minutes the vein has not been accessed, then this will be recorded as a failure of that technique and an alternative method of access used.

Secondary outcome measures Not provided at time of registration

Overall study start date 19/04/2004

Completion date 31/03/2005

Eligibility

Key inclusion criteria

Children undergoing cardiac catheterisation under general anaesthesia who require femoral venous access for the procedure

Participant type(s)

Patient

Age group Child

Sex Both

Target number of participants Approximately 30 patients will be required in each group for an alpha of 0.05 and beta 0.8.

Key exclusion criteria Does not meet inclusion criteria

Date of first enrolment 19/04/2004

Date of final enrolment 31/03/2005

Locations

Countries of recruitment England

United Kingdom

Study participating centre Birmingham Children's Hospital Birmingham United Kingdom B4 6NH

Sponsor information

Organisation Department of Health

Sponsor details

Richmond House 79 Whitehall London United Kingdom SW1A 2NL

Sponsor type

Government

Website http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type Hospital/treatment centre

Funder Name Birmingham Children's Hospital NHS Trust (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