

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

<b>Submission date</b> 30/09/2004	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 30/09/2004	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 29/04/2016	<b>Condition category</b> Surgery	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

**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

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