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Peripheral Intravenous Catheterisation in Obstetric Patients: comparing dorsum of the hand vein with lower forearm vein

Submission date
22/04/2013

Recruitment status
No longer recruiting

Registration date
07/05/2013

Overall study status
Completed

Last Edited
07/05/2013

Condition category
Pregnancy and Childbirth

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Peripheral intravenous catheter insertion (putting in a drip) is a near universal procedure for pregnant women admitted to the delivery suite. The catheter is inserted for a variety of reasons including for blood tests, fluids or medicines to be given intravenously or as a precautionary measure in the event of a major haemorrhage. Doctors usually put the drip on the back of the hand or in the lower forearm. We do know which place is better for the drip to be placed in pregnant women at term. We think that inserting a cannula at the back of the hand is easier but it can be more painful to insert and prone to failure.

Who can participate?
Women at term with a singleton viable pregnancy admitted to the delivery suite who have suitable veins at the back of the hand and the lower forearm for cannula insertion and who need to have a drip inserted according to usual clinical practice will be invited to participate

What does the study involve?
If you agree to take part, you will need to sign a consent form. The doctor will then insert the catheter in the back of your hand or in a lower forearm vein (usually at the wrist) according to random allocation (an envelope containing the allocation will be opened to reveal the site). The catheter will be inserted and secured using standard techniques. Blood is usually taken from the catheter for any blood test you need. An infusion may be started if you need this immediately. If not, 5 ml of normal saline is used to flush the catheter to make sure it is correctly placed and is patent. If the allocated insertion is unsuccessful, your doctor is free to make a second attempt anywhere according to his best judgment.

What are the possible benefits and risks of participating?
No specific risk is anticipated. Both sites are commonly used for the insertion of an intravenous drip.

Where is the study run from?
The study is conducted in the Delivery Suite of the University of Malaya Medical Centre, a tertiary referral hospital with full-fledged operating theatres and neonatal intensive care unit.

When is the study starting and how long is it expected to run for?
The trial is scheduled to start 1 May 2013 and is expected to be completed within 12 months.

Who is funding the study?
Internally by the University of Malaya (Malaysia)
Who is the main contact?
Professor PC Tan
pctan@um.edu.my

Contact information

Type(s)
Scientific

Contact name
Prof Peng Chiong Tan

Contact details
Department of Obstetrics & Gynaecology
Faculty of Medicine
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Malaysia
50603

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
975.12

Study information

Scientific Title
Peripheral Intravenous Catheterisation in Obstetric Patients: comparing dorsum of the hand vein with lower forearm vein: a randomised controlled trial

Acronym
PICOP

Study objectives

Peripheral intravenous catheterisation in women at term admitted to the delivery suite is more likely to be successfully accomplished but is more uncomfortable when attempted through a vein at dorsum of the hand compared to a vein at the lower forearm.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval from the University of Malaya Medical Centre Medical Ethics Committee. Approval number 975.12 dated 12 March 2013.

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
Common medical procedure: Peripheral Intravenous Catheterisation

Interventions
Attempted catherisation with a 18G peripheral intravenous cannula using standard insertion technique without any local anaesthesia into a
1. Vein at the dorsum of the hand or
2. Vein at the lower forearm

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Successful insertion (defined as full placement of the catheter into a vein at the allocated site after a single skin prick confirmed with a straightforward 5 ml saline flush)
2. Insertion pain score using a visual numerical scale from 1 to 10 (1 no pain to 10 worst pain

imaginable)
3. Catheter malfunction (defined as the need for further catheterisation prior to discharge due to deemed unsatisfactory performance of the per protocol indwelling catheter)

Secondary outcome measures
1. Causes of catheter malfunction (if any)
2. Providers insertion difficulty grading
3. Patient satisfaction score with site of catheter placement
4) Patients preference catheter placement site (post catheter removal)
5) Insertion site complications (at hospital discharge)
a. Swelling
b. Bruising
c. Tenderness
d. Thrombosed vein
6) Patient perception of pain at insertion site after removal of catheter scored using a visual numerical scale from 1 to 10 (1 no pain to 10 worst pain imaginable)

Overall study start date
01/05/2013

Completion date
30/04/2014

Eligibility

Key inclusion criteria
1. Admission to the delivery suite
2. Established need for a peripheral intravenous catheter based on usual practice/indication
3. Aged ≥ 18years
4. erm Pregnancy (≥ 37 wks)
5. Singleton, viable fetus
6. Suitable veins at BOTH proposed sites as assessed by the provider who will attempt the insertion

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
At least 304 women

Key exclusion criteria

1. Women who are seriously ill, requiring more than one venous access
2. Women who are scheduled to undergo a Caesarean delivery

Date of first enrolment
01/05/2013

Date of final enrolment
30/04/2014

Locations

Countries of recruitment
Malaysia

Study participating centre
Department of Obstetrics & Gynaecology
Kuala Lumpur
Malaysia
50603

Sponsor information

Organisation
University of Malaya (Malaysia)

Sponsor details
Lembah Pantai
Kuala Lumpur
Malaysia
50603

Sponsor type
University/education

Website
http://www.um.edu.my/

ROR
https://ror.org/00rzspn62

Funder(s)

Funder type

University/education

Funder Name
University of Malaya (H-20001-00-E000066) (Malaysia)

Alternative Name(s)
University of Malaya, University Malaya, Malayan University, UM

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Malaysia

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