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Comparing use of an artery in the wrist to an artery in the groin to access the blood vessels leading to the brain for cerebral angiography (visualising blood flow in the brain)

Submission date
17/09/2019

Recruitment status
No longer recruiting

Registration date
20/09/2019

Overall study status
Completed

Last Edited
03/09/2021

Condition category
Circulatory System

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Cerebral angiography is a test where a thin plastic tube is placed inside the arteries of the neck and contrast dye is injected so that X-ray machines can take pictures of the blood vessels in the brain. It is the best quality of imaging that can be done for some diseases like stroke and brain aneurysms. Traditionally this tube is placed in the vessels by accessing the main artery in the upper thigh/groin - the femoral artery. Heart doctors have found that using the wrist artery (radial artery) has a lower chance of a complications such as bleeding at the access site compared with groin access. For brain angiogram studies, there are concerns that using the wrist may not allow the doctors to get the tube to the neck arteries sucessfully due to the angles involved.
This study aims to show that using the wrist artery for access is as good as and not worse than using the groin artery to succesfully perform a brain angiogram.

Who can participate?
Adults whose doctors have referred them for a brain angiogram as part of their usual treatment and diagnosis (e.g. patients with brain aneurysms). As long as the patients have good quality arteries in their wrist, they can take part in the study.

What does the study involve?
Half of the patients will be randomly allocated to wrist access and the other half to groin access. The angiogram will then be done in the usual way and the results will be compared.

What are the possible benefits and risks of participating?
The possible benefit from being randomly placed in the wrist access group is that patients can sit up after the procedure rather than having to lie flat for 4 hours, and the wrist access is usually more comfortable. The risk is that we may not be able to get access to all the arteries we need for the test (thought to be up to 15% risk from earlier studies), and these patients would then need to have groin access as well (therefore needing two punctures).

Where is the study run from?
Toronto Western Hospital (Canada)

When is the study starting and how long is it expected to run for?
May 2019 to April 2020

Who is funding the study?
There are no additional costs involved in the trial. The usual costs of performing the procedure are incurred by the University Health Network, Toronto which is then in turn funded by Health Canada and OHIP.

Who is the main contact?
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Contact information

Type(s)
Scientific

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Type(s)
Public

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Additional identifiers

Protocol serial number
1.0

Study information

Scientific Title
Transradial versus transfemoral access for cerebral angiography: non-inferiority study

Study objectives
Radial artery access is non-inferior to femoral artery access for achieving procedural success with cerebral angiography

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 25/06/2019, University Health Network Research Ethics Board (10th Floor, Room 1056, University of Toronto, 700 University Ave, Toronto, Ontario, M5G 1Z5; +1 416 581 7849; reb@uhnresearch.ca), ref: 19-5299.0.1

Primary study design
Interventional

Study design
Prospective randomized controlled pilot study (open-label); single center; non-inferiority analysis

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Neurovascular diseases

Interventions
Permuted block randomization will be performed prior to commencing the study using a block size of 4 subjects (with 2 treatment arms: radial and femoral) using the statistical software StatsDirect Version 3.1.22 (Cambridge, UK; www.statsdirect.com).
The results of the randomization will then be used to create a series of sealed envelopes labelled on the front with the study ID number, and inside containing a sheet of paper outlining the group allocation (RADIAL or FEMORAL), as well as the subject data collection sheet pre-filled with the subject ID as the only patient identifier. These envelopes will be placed in numerical order (1 at top, 80 at bottom; 4 additional envelopes created in case of patients who are randomized and then withdraw from the study after group allocation but prior to the procedure). The box containing these envelopes will be kept in the secure area of the angiography suite control room in the Department of Neuroradiology, TWH (Level 3 East Wing).

For adult patients referred to the Department of Neuroradiology for diagnostic cerebral angiography, informed written consent for participation in the trial will be obtained from the patient or their next of kin (where applicable) by one of the co-investigators.

An Allen's test will be performed on the right wrist/hand after obtaining consent but prior to randomization, to determine suitability for radial artery access. If, upon release of pressure from the ulnar artery and opening of the hand, there is not adequate skin reperfusion (restoration of redness) in the index finger within 10 seconds, the patient will be deemed unsuitable for radial artery access and excluded from the study analysis prior to randomization.

Randomization will then be undertaken by the interventionist selecting the top sealed randomization envelope from the box of envelopes in the angiography suite control room. The patient will be notified of their group allocation prior to the procedure.
Based on this result, the angiography suite and equipment will be prepared accordingly for either primary radial access or femoral access, and the radiographers and nursing staff informed of the group allocation to allow for appropriate room setup. If the patient is allocated to the radial group, 1% lidocaine topical cream will be applied to the right wrist overlying the distal radial artery and a waterproof adherent dressing applied to maintain contact with the skin, at least 10 minutes prior to arterial puncture.
The patient will be transferred to the angiography suite for the procedure. Based on the clinical indications for the study and the results of non-invasive imaging, the interventionist will mark on the study data sheet the pre-defined vessels that require angiography for procedural success (e. g. all 6 vessels for exclusion of dural AV fistula, bilateral internal carotid arteries and dominant right vertebral artery for exclusion of intracranial aneurysm etc.).

Radial access group:
The interventionist will perform sonographic assessment of the right wrist volar surface over the distal radial artery to assess the vessel size (minimum internal vessel diameter of 2.0 mm required for successful placement of a 5Fr radial GlideSheath which has an external diameter of 6Fr = 2.0 mm). If the radial artery internal diameter is <2 mm, the patient will immediately crossover to femoral access (and this will indicate procedural failure for radial access with an intention-to-treat analysis).

The right arm (except in cases where the left vertebral artery is the most important vessel to assess on clinical grounds, in which case the left radial artery will be punctured) will be placed in a specifically designed arm-holder for radial access that is available in the neuro-angiography suite with the arm placed approximately 20-30 degrees lateral to the body. Sterile prep and drape will be applied to the right wrist volar surface with the forearm in supination, as well as the right inguinal crease in case of crossover, with a dual-access port whole body angiography drape applied over both sites. Under sonographic guidance in the transverse plane using a linear transducer, 1-2 mL of 1% lidocaine will be injected subcutaneously superficial to the radial artery, at a level 2-3 cm proximal to the radial styloid.

A micropuncture set with a 21g access needle and 0.021in microwire would be used to gain arterial access to the radial artery under ultrasound guidance using single wall puncture, wire position confirmed on fluoroscopy, and a 5Fr radial GlideSheath exchanged for the needle using standard Seldinger technique. A cocktail of 2000 U heparin, 2.5 mg verapamil, and 100 microg nitroglycerin (diluted with the patient's blood from the sheath side port up to a volume of 10 ml to reduce pain during administration) would be slowly infused through the sheath over 2 min to reduce the risk of radial artery spasm or occlusion, and then retrograde contrast digital subtraction angiography (DSA) performed via the sheath to assess the status of the radial artery. Cerebral/supra-aortic angiography would then be performed using the 5Fr Simmons 2 Glidecath (100-cm length; Terumo Inc., Japan) as the main catheter, with selection and angiography first of the right vertebral artery (if required) +/- the left ICA in patients with a 'bovine' anatomical variant arch, prior to formation of the secondary curve within the aortic arch for selection of the remaining vessels, over an 0.035-in 150-cm length angled glidewire (Terumo Inc., Japan). Use of

Simmons 3 GlideCath's or other neuro-angiography catheters is allowed if the Simmons 2 catheter is unsuccessful for vessel cannulation. Conversion to femoral artery access would be undertaken at the discretion of the interventionist in the setting of failed radial artery access or failed access to the pre-defined supra-aortic vessels required for the diagnostic angiographic study. Haemostasis at the end of the procedure would be achieved using a TR BAND (Terumo Inc., Japan) compression wristband, inflated to 15 ml of air for 2 h, and then followed by serial removal of 3 ml of air from the band every 15 minutes until empty.

Femoral access group:
Ultrasound guided access using modified Seldinger technique with insertion of a 5Fr sheath to the right common femoral artery, with prior administration of local anesthesia (1% lidocaine 2-3 ml). Angiography to be performed in a standard fashion as per the interventionists usual technique. Manual compression over the femoral head of the common femoral artery for haemostasis at the end of the procedure for at least 10 min. The use of a vascular closure device would be at the discretion of the interventionist (6Fr AngioSeal). Post-procedure bedrest instruction as per usual Department protocol (minimum 4 h). This protocol is based on the existing standard of care in the Department of Neuroradiology at TWH (UHN).

Post-procedure
At 1 h post procedure, within the Medical Imaging Day Unit (or on the patient's ward if appropriate), the post-procedure access site pain will be assessed using the Visual Analogue Scale (VAS: a 100 mm linear scale with cm and mm markings, where the patient indicates their discomfort by pointing with their index finger on the line what their current level of discomfort is) and the result marked on the study data sheet by the investigator or treating MIDU nurse.

Follow-ups
After discharge home or to the admitting ward from the MIDU, no further follow-up is required. No study visits are required other than at the time of the procedure.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Rate of procedural success (defined by successful cannulation and angiography of pre-defined vessels based on diagnostic requirements). Efficacy will be assessed via procedural success rates (binary variable) for both groups, with between-group comparison performed using non-inferiority testing (non-inferiority limit of 10% procedural failure).

Key secondary outcome(s)
1. Visual analogue scale (VAS) assessment of post-procedure pain from the access site, measured 1 h post-procedure. The means for the two groups will be compared using an unpaired t-test (alpha = 0.05). A >10% difference in the mean values of the VAS results between groups would be indicative of significant clinical difference.

Completion date
30/04/2020

Eligibility

Key inclusion criteria

1. Aged ≥18 years
2. Referred to the Department of Neuroradiology (UHN) for diagnostic cerebral angiography
3. Ability to give informed written consent to participate in the study, or have a next of kin present (phone consent will not be deemed satisfactory) to give such consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Total final enrolment
80

Key exclusion criteria
1. Aged <18 years
2. Presence of an arterio-venous fistula for hemodialysis over the right upper limb
3. Previous radial artery grafting from the right upper limb for vascular/cardiovascular surgery
4. Known prior dissection or occlusion of the right radial, brachial, or subclavian arteries
5. Known prior severe anaphylactoid reaction to intravascular iodinated contrast injection
6. Known severe uncorrected coagulopathy
7. Inability to give written informed consent or absence of next of kin in the MIDU to give consent for study participation
8. Failed Allen’s test prior to randomization

Date of first enrolment
23/09/2019

Date of final enrolment
23/03/2020

Locations

Countries of recruitment
Canada

Study participating centre
Toronto Western Hospital, University Health Network
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Sponsor information

Organisation
University Health Network (Toronto Western Hospital)

ROR
https://ror.org/042xt5161

Funder(s)

Funder type
University/education

Funder Name
University Health Network

Alternative Name(s)
The University Health Network, UHNToronto, Toronto Hospital, Ontario Cancer Institute /Princess Margaret Hospital, RÉSEAU UNIVERSITAIRE DE SANTÉ, UHN

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Canada

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from:
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Further approval from the UHN Research Ethics Board would be required before the data can be released to third parties.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		29/12/2020	03/09/2021	Yes	No