

Participant Information Sheet

Version February 2022

Randomised controlled trial of tourniquet associated pain generated in lower limb after exsanguination by Esmarch bandage versus leg elevation ?

We invite you to take part in a research study

- Before you decide whether to take part in our study, it is important for you to understand why the research is being done and what it will involve.
- Please take the time to read the following information carefully. Discuss it with friends and family if you want their thoughts.
- You are free to decide whether or not to take part in this study. If you choose not to take part, it will not affect the care you get from your own doctors.
- You are free to leave the study at any time and we will not ask you for any explanation.
- Please ask us if anything is not clear or if you would like more information.

Important things that you need to know

- We want to find out which is the most comfortable way for surgeons to use a tourniquet.
- We will only need you for a maximum of two (2) hours.
- You will need to have a tourniquet applied to both arms at the same time.
- There will be no surgery / treatment as part of the study.
- There will be no follow-up.
- We will not record any personal data that will identify you.
- We will not look at your medical notes.
- We will not notify your GP about your participation.
- You can stop taking part in the study at any time.

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How to Contact Us

If you have any questions about this study, please talk to the team that organised it:

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Why are we doing this study?

- Doing simple procedures after numbing the leg with people awake, means they don't have to stay overnight in hospital, the procedure takes less time, and we can then reduce the time people have to wait for their operations.
- Using a tourniquet for leg, ankle or foot surgery controls any bleeding and allows surgeons to see all the nerves, blood vessels and other structures clearly.
- Even though the leg is numbed, some people find the feeling of having the tourniquet squeezing their legs is uncomfortable.
- Usually surgeons will lift up the leg (elevate) of the person they are operating on before they inflate the tourniquet to drain the blood from the leg and improve their view for the surgery. However, some surgeons claim, that by rolling an inflated hollow rubber tube (Rhys Davies exsanguinator) up the thigh before inflating the tourniquet (exsanguination), they can squeeze even more blood out of the arm and achieve much clearer views .
- We are looking at the tolerance levels of these two (2) methods to determine if one method (elevation) is more comfortable than the other (exsanguination).

What do I need to know about the equipment being used for the study?

Tourniquet: A tourniquet is a device used to squeeze an leg and is routinely used to stop bleeding. We will be using an electronic tourniquet which is a machine with a cuff attached to an electronic control panel that inflates the cuff and controls the pressure. The cuff is placed around the thigh. There will be a layer of padding placed directly onto the skin before the cuff is applied. We will calculate the correct pressure for the cuff using your blood pressure readings. As the tourniquet is inflated you will feel a pressure around the thigh under the tourniquet followed by a dull aching sensation. You may also feel some pins and needles or some numbness. If at anytime you feel too uncomfortable, we will deflate the cuff and remove the tourniquet. We will not repeat the inflation once we deflate the cuff.

Rhys-Davies Exsanguinator: Is an inflated rubber tube. Your toes are placed into the centre of the cylinder and the rubber "sausage" is rolled up your leg as far as possible. This will be held in place whilst the tourniquet is inflated. Once the tourniquet is at the correct pressure, it will be rolled back off your leg.

Blood pressure monitor: We will measure your blood pressure before placing the tourniquets so we can calculate the correct pressure for the tourniquet. We will use an electronic blood pressure machine which will squeeze your leg for a very short period and give us a digital reading.

Heart rate monitor: We will use a monitor that gently clips to your ear to monitor your heart rate.

Why am I being asked to take part in this study?

- We are comparing comfort levels only and therefore need healthy volunteers with no arm problems.
- Many people who come in for an operation already have painful foot/ankle/leg and thus it would be difficult to say where any discomfort was coming from.
- Many people coming in to hospital for an operation are anxious and may also be more sensitive to any discomfort.
- We do not want to put anyone at risk with this study, so we need fit, healthy volunteers who are highly unlikely to suffer any adverse side effects from this study.

Are there any potential side effects?

- Most people report a dull ache with the tourniquet inflated but actual discomfort levels vary between individuals.
- There is a small risk of bruising where the tourniquet has been secured. We will place layers of cotton wool under the tourniquet to provide padding and minimise this risk.
- Pins and needles and/or numbness is commonly experienced. We will monitor you carefully, and if at any stage you find these feelings too uncomfortable or upsetting, we will immediately deflate and remove the tourniquet. We will continue to monitor you until normal feeling returns to your leg. If normal feeling has not returned to your leg by 30 minutes, we will accompany you to the Emergency Department.
- Reduced muscle power has been reported in other similar studies, but this was always temporary and passed quickly. We will not be assessing your strength.

More information about taking part

- The study will take place at the Townsville University Hospital outpatient department.
- If you agree to take part in the study, we will provide you with more specific details about where and when to attend.
- You will need to sign a consent form prior to participating.
- We will NOT be consulting any of your medical records and will thus be relying on your assurance that you are fit and healthy. If you have any foot, ankle or leg problems, circulation or nerve problems you will NOT be eligible to take part. **A full list of exclusion criteria is listed on page 4.**
- A flow chart of the sequence of the study is detailed on page 5.

If you suffer from any of the conditions listed below you *CANNOT* take part in this study

Nerve problems

Diabetes, multiple sclerosis, any disease affecting sensation or function

Loss of sensation/altered sensation in the foot, leg or thigh

Weakness of leg, ankle or foot

Compressive neuropathy of lower limbs

Any type of lower limb tendinitis

Hip, knee or ankle dislocation in past 12 months

Previous trauma to hip, knee ankle or foot resulted in deficit muscles power or sensation

Thoracic, lumbar or sacral spine osteoarthritis

Previous injury, trauma or surgery on thoracic, lumbar or sacral spine

Impingement of nerves or disc herniation in thoracic, lumbar or sacral spine

Circulation problems

Sickle cell disease, Raynaud's Syndrome or any other disease that affects circulation

Clotting problems

Any history of blood clots including deep vein thrombosis (DVT) or pulmonary embolism (PE)

High blood pressure (controlled or uncontrolled), medication for high blood pressure

Previous heart attack or stroke

Surgery or fractures within the past 12 months anywhere on the lower limbs including hips, thighs, legs, ankles or feet

Medications Warfarin, Aspirin, Clopidogrel, any other medication affecting blood clotting

Steroids, including inhalers

If you take any medications listed below you *CANNOT* take part in this study

- Warfarin
- Aspirin
- Clopidogrel
- Steroids, including inhalers
- Any medication that thins the blood
- Medication for high blood pressure

