Tourniquet study: Is the high thrombosis risk after knee arthroscopy caused by limb-tourniquet application? A randomized clinical trial into the effect of tourniquet use on the coagulation system.

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To investigate the effect of tourniquet application on the coagulation system in patients undergoing a knee arthroscopy. A finding of more prominent activation of the coagulation system with tourniquet use than with non-use will create an important...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Joint disorders
Study type	Interventional

Summary

ID

NL-OMON40719

Source
ToetsingOnline

Brief title
Tourniquet study

Condition

- Joint disorders
- Embolism and thrombosis

Synonym
blood clot in vein of the leg, Venous thrombosis

Research involving
Human

Sponsors and support

Primary sponsor: Groene Hart Ziekenhuis
Source(s) of monetary or material Support: Afdeling klinische Epidemiologie LUMC;Afdeling trombose en hemostase LUMC en afdeling orthopaedie Groene Hart Ziekenhuis

Intervention

Keyword: Coagulation, Knee arthroscopy, Randomized clinical trial, Tourniquet

Outcome measures

Primary outcome

Data on duration of surgery and duration of tourniquet use will be collected.

Blood collected from the cubital vein and the great saphenous vein during arthroscopy of the knee will be analyzed on outcome parameters that reflect a hypoxic state, an inflammatory reaction, involvement of the endothelium, a procoagulant state and thrombin formation.

Primary markers:

• Prothrombin fragments 1 + 2

• von Willebrand Factor (vWF)

• D-dimer

• P-selectin

• Plasmin Activator Inhibitor 1 (PAI-1)

• pH

• pO2

• pCO2

• Lactate

• White Blood Cell Count (WBCC)

Secondary outcome

• factor VIII

• Thrombin and Antithrombin complexes (TAT)

• Plasmin and antiplasmin complexes (PAP)

• E-selectin

• Tissue plasminogen activator (tPA)

• Thrombomodulin

• Neutrophil extracellular traps (NETs)

Study description

Background summary

Knee arthroscopy is the most commonly performed orthopaedic procedure worldwide, with, according to the American Society for Sports Medicine, over 4 million procedures performed each year. The risk of venous thrombosis following this procedure is considerable with rates of symptomatic events varying between 0.9% and 4.6%.
It is currently unknown how this high risk comes about considering its short duration and minimal tissue damage caused by the procedure. A factor that may play a role is the use of a tourniquet. A large majority of orthopaedic surgeons prefer to operate within a *dry field*, which is obtained by the use of a tourniquet. In the proposed study we will investigate the effect of a tourniquet on local and systemic markers of hypoxia, inflammation, involvement of endothelium, and coagulation activation.

Study objective

To investigate the effect of tourniquet application on the coagulation system in patients undergoing a knee arthroscopy. A finding of more prominent activation of the coagulation system with tourniquet use than with non-use will create an important opportunity to prevent thromboembolic events in these patients, as it has been shown that knee arthroscopy can be performed

adequately without the use of a tourniquet. Furthermore, it will increase our understanding of the pathophysiology of thrombosis.

Study design

In a randomized, controlled clinical study we will compare local and systemic coagulation and inflammation markers before and after knee arthroscopy between two groups: 25 patients will be randomized to arthroscopy with tourniquet (Group I) and 25 patients to arthroscopy without tourniquet (Group II).

Intervention

Patients will be randomized to knee arthroscopy without tourniquet use and to knee arthroscopy with tourniquet use. In patients randomized to arthroscopy with tourniquet use, exsanguination in the leg in which the knee arthroscopy will be performed will be accomplished by raising the leg vertically for one minute. The tourniquet will be inflated to 100-150 mmHg above systolic blood pressure.

Study burden and risks

We will compare two surgical regiments that are currently both used depending on the physician*s or hospital*s preference. The patients in our trial will be subjected to one of these standard treatments. It is therefore not expected that participation will lead to an increased health risk. All patients will need to receive one additional intravenous catheter for blood sampling for the study in the great saphenous vein, next to the intravenous catheter in the arm, which is already in place because of the surgery. This intravenous catheter will be placed after patients have received spinal anaesthesia, to minimize the burden. Blood samples will be taken pre and post-operatively on three different time points. With the use of an intravenous catheter, patients do not require numerous vena punctures. No extra hospital visits are required for the study.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Age of 18 years or older and arthroscopy of the knee for the following indications:
Meniscectomy, diagnostic arthroscopy, removal of corpora libera

Exclusion criteria

• Any kind of coagulation disorder
• pregnant or within 3 months of childbirth
• Use of hormonal anticonception
• A history of venous thrombosis
• Had major surgery in the past two monhts
• A history of cast-immobilization of the lower extremity the past two months
• A neoplasm or inflammatory disease
• A BMI>30
• using anticoagulant therapy
• Any other anaesthesia technique than spinal anaesthesia

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)

Primary purpose: Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	02-09-2015
Enrollment:	50
Type:	Actual

Medical products/devices used

Generic name:	Tourniquet
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	07-04-2015
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL49117.058.14