Balloon test for iliac vein compression

Published: 14-10-2015
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The objective of this study is to identify whether pelvic collateralisation occurs when a temporary acute obstruction is induced in the left common iliac vein of healthy subjects.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Vascular therapeutic procedures
Study type	Observational invasive

Summary

ID

NL-OMON42561

Source
ToetsingOnline

Brief title
Balloon test study

Condition

- Vascular therapeutic procedures
- Vascular disorders NEC

Synonym
iliac vein compression syndrome, may-thurner syndrome

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: balloon occlusion test, iliac vein compression, may-thurner syndrome, venography

Outcome measures

Primary outcome

The main endpoint of this study is the presence of collaterals (passing the midline) after balloon occlusion of the left common iliac vein, which is scored as present or not. (also location and amount if present and expressed as a prevalence percentage)

Secondary outcome

Demographic characteristics

Study description

Background summary

Iliac vein compression is a common cause of leg or abdominal complaints and is difficult to diagnose. Although a combination of duplex ultrasonography, magnetic resonance venography and two-plane phlebography are able to show compression, not all suspected iliac vein compressions can be identified. Intravascular ultrasound appears to have a higher diagnostic value, but is far more expensive. In our experience a balloon occlusion test in the common iliac vein during phlebography can diagnose iliac vein compression due to the collateral network that is visualised. The general consensus is that pelvic collaterals are a sign of pathology, though we would like to validate this test by showing that a balloon occlusion test in healthy subjects does not identify a collateral network.

Study objective

The objective of this study is to identify whether pelvic collateralisation occurs when a temporary acute obstruction is induced in the left common iliac vein of healthy subjects.

Study design

This is a diagnostic study in healthy subjects.

Study burden and risks

The patient can experience some pain and could develop some minor bleeding in the form of a bruise. An allergic reaction is less likely and risk of thrombosis or severe bleeding is highly unlikely

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 18 - 45 years

Exclusion criteria

- Disease affecting the circulatory system, such as cardiac disease, varicosities or peripheral

arterial disease, on the basis of anamnesis.
- History of bleeding or clotting disorders
- Complaints of the abdomen or leg consistent with iliac vein compression syndrome or pelvic congestion syndrome
- CEAP classification of C2 or higher (C0: no venous signs, C1: venectasia, C2: varicose veins, C3: edema, C4: skin changes, C5 healed ulcer, C6: active ulcer)
- History of deep venous thrombosis or pulmonary embolism.
- History of surgery of the abdomen, groin or lower limb
- Pregnancy
- Allergy to contrast or lidocaine
- Active malignancy

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	20-01-2016
Enrollment:	23
Type:	Actual

Ethics review

Approved WMO

Date:	14-10-2015
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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
ClinicalTrials.gov	NCT???(pending)
CCMO	NL54330.068.15