TransvenoUs lead exTRaction and post-ExtraCTion venous occlusion
A single centre, prospective cohort study

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Main objective is to compare the incidence of subclavian vein thromboses after TLE by manual traction alone versus TLE with use of the mechanical rotational dilator sheath in case of fibrous adhesions hampering extraction by manual traction alone....

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Cardiac arrhythmias
Study type	Observational non invasive

Summary

ID

NL-OMON46192

Source
ToetsingOnline

Brief title
UTRECHT

Condition

- Cardiac arrhythmias

Synonym
occusion of subcalvian vein.

Research involving
Human

Sponsors and support

Primary sponsor: Diagram B.V.
Source(s) of monetary or material Support: in eerste instantie door de maatschap er wordt nog financiering vanuit de industrie gevraagd

Intervention

Keyword: Evolution, Lead extractie, venogram, venous occlusion

Outcome measures

Primary outcome

Percentage of subclavian vein occlusion 2 to 3 months post lead extraction

procedure

Secondary outcome

• Assess safety and efficacy of TLE

• Long term follow-up of patients after TLE

• Comparison with historical data

Study description

Background summary

Little is known about venous occlusion post-TLE. Post CIED implantation an incidence of 8-21% of occlusion of the subclavian or brachiocephalic vein is seen (10), however the incidence of pacemaker induced superior vena cava syndrome is reported to be very low, at 0.03-0.4%. Post-extraction however, given the often disruptive nature of freeing the leads from the veins with extraction tools, lead extraction might predispose to thrombosis and venous obstruction in even higher rates. Bracke et al (9) found an 8% incidence of new symptoms suggestive of venous occlusion following lead extraction in patients with a previously patent entry vein. No Venogram post-extraction was performed. Given the underestimation of occlusion by clinical symptoms, the incidence of total occlusion could still be higher. Recent study (11) showed 15.6% microscopic vein injuries during lead extraction, especially when a laser sheath is used. This is representative for the vascular injury inflicted during TLE.

Study objective

Main objective is to compare the incidence of subclavian vein thromboses after TLE by manual traction alone versus TLE with use of the mechanical rotational dilator sheath in case of fibrous adhesions hampering extraction by manual

traction alone.
Secondary objective is to assess safety and long term follow-up in patients after TLE and comparison with historical data.

Study design

Single Centre prospective cohort study designed to enrol 201 patients

Study burden and risks

A venogram is an x-ray test that involves injecting contrast material into a vein to assess the lumen of the vein. Although the procedure is relative save, X-ray and venous injection has risks. Contrast nephropathy is a generally reversible form of acute kidney injury (AKI) that occurs soon after the administration of radiocontrast media. The increased creatinine is generally observed within 24 to 48 hours after contrast exposure and is mild. The creatinine usually starts to decline within three to seven days. The doses of contrast is relatively low.
In the current guidelines there is no recommendation for standard care after TLE. In our hospital we frequently assess the subclavian vein with a venogram to exclude venous thrombosis, from 2014 on post procedure venogram was frequently performed. In this study we will regulate the care for lead extraction patients by performing a routine venogram post TLE in order to assess predictors for venous thrombus/embolus.

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

All patient in need for trans venous lead extraction at the Isala Hospital

Exclusion criteria

Not able or willing to give informed consent

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	03-12-2018
Enrollment:	201
Type:	Actual

Ethics review

Approved WMO Date:	15-11-2018
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)

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	NL66680.075.18