Duplex-guided PTA (DuPTA) versus conventional PTA utilizing contrast in peripheral artery disease: Randomised control trial

Published: 31-05-2013
Last updated: 19-03-2025

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Ethical review	Approved WMO
Status	Completed
Health condition type	Vascular therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON38478

Source
ToetsingOnline

Brief title
DuPTA Vs contrast PTA: RCT

Condition

- Vascular therapeutic procedures
- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
atherosclerosis, Peripheral arterial disease (PAD)

Research involving
Human

Sponsors and support

Primary sponsor: Atrium Medisch Centrum
Source(s) of monetary or material Support: Er is geen financiering voor het onderzoek.

Intervention

Keyword: - Duplex-guidance, - PTA, - Randomised control trial

Outcome measures

Primary outcome

Primary outcome measure:

* Procedural success (passing the stenotic lesion with the guide wire and the

dilatation or stenting of the lesion

* Clinical success (50% reduction in Peak Systolic Velocity (PSV) or

subjectively without symptoms two weeks after the procedure)

Secondary outcome

Secondary outcomes:

* Duration of intervention (time of puncture - close)

* Pain (per-and postoperatively using standardized analog VAS pain score)

* Patient satisfaction

* complications (bleeding, infection, re-intervention, dissection, for 30 days)

* Recovery time (days to full return to work).

Study description

Background summary

Recent publications of duplex-guided percutaneous transluminal angioplasty (PTA) have shown that this relatively new technique is safe and efficacy 1-9. For the treatment of significant arterial stenosis in patients with symptomatic

peripheral arterial disease. Recent own research, were 45 significant stenoses were treated in symptomatic patients with stenotic arterial disease have confirmed these earlier results.
All these studies are descriptive studies of patients with symptomatic peripheral arterial disease treated by duplex guided PTA. To date, no randomized controlled studies that conventional PTA with contrast compares with duplex-guided PTA.

Study objective

The aim of the research is to demonstrate a possible significant difference in procedural success and / or clinical success of duplex-guided PTAs compared with conventional PTA in an RCT.

The study describes the above hypothesis and has led to the creation of the following study. Preoperative informed consent will be obtained before patients were randomized into 2 groups. Group 1 will consist of the PTA with conventional contrast, group 2 is guided to the duplex-PTA. Randomisation will take place after obtaining informed consent, and patients are needed. For more information about the radomisatie procedure please refer to section 5.1.4.

Study design

This study was designed as a prospective study in which two groups are randomized. Group 1 will consist of the PTA with conventional contrast, group 2 is guided to the duplex-PTA. Randomisation will take place after obtaining informed consent. Patients will be assigned a number of follow-up, patient 1, number 1, etc.

The entire process, pre-and post-operatively will be identical to the current clinical practice. Patients with an indication for PTA will be discussed in multidisciplinary consultation, will the local radiologists and vascular surgeons. If such indication is given, the patient at the clinic will be given explanations regarding the proposed intervention. If the patient(e) agree to these proposed intervention, a member of the research team (Drs. TA Sigterman, Dr. LH Bouwman, Dr. R. Welten, Drs A. Krasznai) will inform the patient about the above described study. . After explanation, the patient will be given at least 1 week to consider. After this, Drs. TA Sigterman will contact the patient to determine whether patient (e) wants to participate in the study. Any questions will be discussed and answered in a face-to-face conversation, and informed consent will be signed if patient consent. If patient informed consent granted, patient will be randomized and for the relevant intervention planned. If patient does not wish to participate, patient (e) will be regular intervention. If the patient refrain from participation shall not otherwise affect his or her treatment and the therapeutic relationship between doctor and patient.

Of all included patients, the baseline data are listed which are important for study in a pre-made standard form. Also, in all patients using the standardized VAS analog pain score will be measured to determine how much pain they have, this will be done perioperatively and postoperatively on the day after the procedure are recorded. We also will look at content and restore to functionality. These will be assessed with a questionnaire.
The follow-up will be carried out by the members of the research (Drs. TA Sigterman, Dr. LH Bouwman, Dr. R. Welten, Drs A. Krasznai). Patients will be seen 4 weeks postoperatively at routine control clinical follow-up, whereby they can indicate the degree of satisfaction of the VAS pain score. Routine duplex examination of the treated lesion will for outpatient visits are made. In addition, the time required to return to work and restoration of the functionality can be viewed. Patients participating in the study will be no additional examinations. This means, no additional laboratory tests and no additional studies.

Intervention

Procedure contrast PTA
Conventional PTA is not different from current clinical course. Patients report sober in the morning, the day of the planned intervention included the (Day Care / Fasting recording unit) (Ward 1West). Where they are prepared, according to local protocol here they receive any necessary medication (Protocol preoperative administrative actions / Fasting admissions, day care, sober recording unit). After which they will undergo the PTA procedure in the angio suite. This procedure will be performed by an interventional radiologist (R. Heijboer, L. Leeuw) or vascular surgeon (LH Bouwman, A. Krasznai, R. Welten). After the procedure, patients are brought to ward 11-12 (Protocol Angio Room transfer after PTA to nursing). Here there will be frequent checks are carried out in the Ward 11/12, according to local protocol (Protocol Angiography aftercare PTA and intervention). 1 day postoperatively, each patient will undergo a routine duplex examination of the treated lesion (angioplasty stenosis), to determine the Peak Systolic Velocity (PSV). This research will be conducted on the KNF. There will be no specific employees be designated for these studies to be performed blinded. On the application will only be listed PTA, so that the vascular technicians of the KNF are not aware of which treatment the patients have undergone . If the patient recovers adequate he/she will be discharged the same day, if the ward doctor deems this possible. This is not different from current clinical course.

Procedure Duplex PTA
Duplex-guided PTA is not different from current clinical course. Patients report sober in the morning, the day of the planned intervention on the (Day Care / Fasting recording unit) (Ward 1West). Where they are prepared, according to local protocol here they receive any necessary medication (Protocol: preoperative administrative actions / Fasting admissions, day care, sober

recording unit). After which they will undergo the PTA, the operating procedure will take place under spinal anesthesia. This anesthesia is administered by the attending anesthesiologist. The PTA procedure will be performed by vascular surgeons (A. Krasznai, LH Bouwman), in collaboration with two vascular technicians of clinical neurophysiological function lab (KNF). These two employees will assist in visualizing the arterial stenotic lesions with duplex. After the intervention, all patients will be monitored at the recovery until the attending anesthesiologist approves the transfer of the patient (e) to the regular section (Ward 11-12) (Protocol: Dismissal Criteria Recovery). The department will frequent checks take place according to local protocol (see Annex protocol PTA Atrium MC Heerlen). 1 day postoperatively, each patient will undergo a routine duplex examination of the treated lesion (angioplasty stenosis), to determine the Peak Systolic Velocity (PSV). This research will be conducted on the KNF (floor 3). There will be no specific employees be designated for these studies to be performed blinded. On the application will only be listed PTA, so that the vascular technicians of the KNF are not aware of which treatment have undergone patients. If the patient recovers adequate he/she will be discharged the same day, if the ward doctor deems this possible. This is not different from current clinical course.

The entire process, pre-and post-operatively will be identical to the current clinical practice.
Patients will be discussed in the multidisciplinary consultation with a local indication, the interventional radiologists (Drs. R. Watson, Drs. L. Lion) and vascular surgeons (Dr. LH Bouwman, Dr. R. Welten, Drs A. Krasznai) the indication for angioplasty standard set stenotic lesions. If this indication is given, the patient will get the police explanation of the proposed intervention. If patient (e) agree to the proposed intervention will be a member of the research group (Drs. TA Sigterman, Dr. LH Bouwman, Dr. R. Welten, Drs A. Krasznai) patients on the above research in an interview at the outpatient clinic . After explaining the patient's patient with us and at least one week to think. After this week to think will Drs. TA Sigterman patient contact by telephone to determine whether patient (e) to participate in the study. Any questions will be discussed and answered in a face to face conversation, after which it will be if patient gives consent. Signed informed consent If patient informed consent granted, and will be scheduled for that intervention. Patient randomized If patient does not wish to participate will be patient (e) regular scheduled. If the patient refrain from participation has no effect on his or her treatment and the therapeutic relationship between doctor and patient.

Of all patients included, the baseline data are recorded that are important for study in a pre-made standard form (see Appendix). Will also be in all patients using the standardized VAS analog pain score determines how much pain they have, this will perioperative and postoperative be registered on the day after surgery (see Annex). Will also be looked at satisfaction and restore functionality. These will be assessed with a questionnaire (see Appendix).

The follow-up will be performed by members of the research group (Drs. TA Sigterman, Dr. LH Bouwman, Dr. R. Welten, Drs A. Krasznai). Patients will come in weeks postoperatively routine, which they can indicate in the VAS pain score. Satisfaction levels Routine duplex examination of the treated lesion will be made two weeks after the intervention. For outpatient visit Also, the length of time to return to work and restoration of the functionality to be viewed. Patients participating in the study will not undergo additional tests. Here it is intended, no additional laboratory tests and no additional studies. See Appendix schedule described above scores.

Study burden and risks

This study does not burden the participants. Given that the two treatment options do not differ from current practice, we expect that patients experience no additional burden through participation in the study. There is no additional outpatient visits, investigations or interventions.

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

* Patiënts (above 18 years of age or older)
* Indication for PTA in significant stenotic peripheral artery disease

Exclusion criteria

- No duplex-visualization possible
- arterial occlusion

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	11-07-2013
Enrollment:	142
Type:	Actual

Ethics review

Approved WMO

Date:	31-05-2013
Application type:	First submission
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 27553
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL44471.096.13
OMON	NL-OMON27553