Does the use of paclitaxel coated balloons inhibit restenosis in hemodialysis fistula? Results compared to conventional PTA balloons in a randomised trial.

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Arteriosclerosis, stenosis, vascular insufficiency and necrosis
Study type	Interventional

Summary

ID

NL-OMON36632

Source
ToetsingOnline

Brief title
Paclitaxel coated balloons in hemodialysis fistula

Condition

- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
"Hemodialysis fistula stenosis" "Vessel narrowing in fistula of dialysis patiënten"

Research involving
Human

Sponsors and support

Primary sponsor: Albert Schweitzer Ziekenhuis
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Hemodialysis fistula, PTA, Stenosis

Outcome measures

Primary outcome

Primary endpoints are 12-months patency of the use of placlitaxel coated balloons and conventional balloons. Endpoints being re-intervention, more than 50% stenosis of the treated segment of the hemodialysis fistula, occlusion of the fistula at duplex ultrasound and blood flow below 600 ml/min.

Secondary outcome

Secondary endpoints are initial angiographic success (less than 30% stenosis), peri-procedural complications (within 24 hrs) and late complications (within 30 days). Further secundairy endpoint are time to hemostasis of the puncture site and diameter of hematoma arond the puncture site. Complications include balloon rupture, vessel disruption, significant bleeding, hypotension, allergic reaction, infection, pulmonary embolus, hand ischemia, occlusion and thrombosis of the fistula, immediate surgical intervention and death. Also evaluation with duplex US at 2 weeks, 3, 6, and 24 months will be taken into accopunt as secondary study outcome.

Study description

Background summary

Dialysis Outcomes Quality Initiative (DOQI) guidelines recommend percutanous transluminal balloonangioplasty (PTA) for the treatment of significant stenoses in hemodialysis fistula. The initial results of PTA are often excellent. However, midterm patency is only average (6-months primary patency of 38% to 55%). Secondary patency can be kept at an acceptable level by repeating the PTA procedure. Improving primary patency of PTA could prevent repeated PTA treatments. Restenosis after PTA is caused by intima hyperplasia, produced by the smooth muscle cells in the vessel wall. Through infiltration of the vessel wall with the paclitaxel, paclitaxel coated balloons should inhibit the proliferation of smooth muscle cells, and thereby prevent intima hyperplasia formation. Significant inhibition of restenosis has already been established in the coronary arteries and the superficial femoral arteries. Our hypothesis is that the use of paclitaxel coated balloons in stenoses of hemodialysis fistula should increase the primary patency of PTA significantly.

Study objective

Our objective is to evaluate the patency of paclitaxel coated balloons in hemodialysis patients presenting at the radiology department more than once a year with repetitive severe stenoses of their fistula, and compare the results with primary patency of conventional balloons.

Study design

Randomised multi-centre study with patients and observers blinded for patient data.

Intervention

PTA of the vein of the hemodialysis fistula using a placlitaxel coated balloon or a conventional balloon.

Study burden and risks

Risks and complications of PTA include disruption of the vessel wall and a sporadic pulmonary embolus. Thus far it has never been reported that PTA using a paclitaxel coated balloon causes more complications than PTA with the use of a conventional PTA balloon. With the removal of the sheath after the procedure and subsequent pressure at the puncture site a rebleed or hematoma could occur. The use of paclitaxel could potentially increase blood plasma levels of paclitaxel. Reported blood plasma concentrations after the use of paclitaxel coated balloons all remained below the level of 0.01 mg/ml. Furthermore, it was established that pharmacodynamic parameters of paclitaxel were independent of renal function. Patients will be asked to undergo duplex ultrasound examinations of their fistula at 2 weeks, 3, 6, 12 and 24 months after

treatment. Further, baseline characteristics will be noted.

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

Hemodialysis patients presenting more than once a year with repetitive severe stenoses of the draining vein of the fistula, evaluated with duplex ultrasound and reconfirmed at angiography. Patients with a life expectancy of at least one year will be included.

Exclusion criteria

Refusal or no motivation to participate in the study or receive PTA treatment. Pregnancy or

planing to become pregnant during the study. Known allergic reactions in the past with regard to iodinated contrast agents, paclitaxel, heparine or aspirine. Under 18 years of age.

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	07-04-2011
Enrollment:	54
Type:	Actual

Medical products/devices used

Generic name:	Paclitaxel-eluting Balloon Catheter
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	17-12-2010
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO

Date:	17-02-2011
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	09-09-2011
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	01-06-2012
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	28-06-2012
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL33371.100.10