

# 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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<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Arteriosclerosis, stenosis, vascular insufficiency and necrosis
<b>Study type</b>	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 paclitaxel 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 secondary endpoint are time to hemostasis of the puncture site and diameter of hematoma around 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 account as secondary study outcome.

## Study description

### Background summary

Dialysis Outcomes Quality Initiative (DOQI) guidelines recommend percutaneous 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 paclitaxel 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

### Public

Albert Schweitzer Ziekenhuis

Albert Schweitzerplaats 25  
3318 AT Dordrecht  
NL

### Scientific

Albert Schweitzer Ziekenhuis

Albert Schweitzerplaats 25  
3318 AT Dordrecht  
NL

## 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