

Clinical Trial: Pilot Study to Evaluate the Safety and Preliminary Efficacy of the Peritec Peritoneal Lined Stent and Delivery System

(Lower Extremity Arterial Disease Treatment Study)

07/05/2008

Sponsoring Company:

- PeriTec Biosciences (Cleveland Clinic Foundation)

Product:

- Peritoneal Lined Stent (PLS)

Objective:

- To determine the safety and effectiveness of the Peritoneal Lined Stent in keeping th Superficial Femoral Artery open and allowing blood to flow in the leg.

Trial Status:

- Recruiting

Trial Phase:

- I

Inclusion Criteria:

- Patient with claudication or ischemic rest pain(Rutherford Categories 2-4)
- The angiogram will need to have been performed confirming superficial femoral artery short segment occlusion(<5cm first two patients and <10cm there on) or high grade(>50%)stenosis
- Patient has a signed and dated informed consent
- Patient has a resting ABI <0.9 or an abnormal exercise ABI if resting ABI is normal. Patients with incompressible arteries (ABI >1.2) must have TBI <0.8
- Life expectancy greater than one year
- The ability to comply with protocol follow up requirements and required testing
- Angiographic lesion requirements assessed at time of procedure
 - Lesion of the superficial femoral artery with a short segment occlusion(<5cm first two patients and <10cm there on) or high grade (>50%) stenosis
 - Target lesion 1 cm below profunda/superficial femoral artery origin and 3cm above knee joint
 - Angiographic evidence of a minimum of at least one tibial with continuous artery runoff to the ankle that does not require intervention
 - Guidewire has successfully traversed lesion and is within the true lumen of the distal vessel, and successful placement of 9 french(Fr) sheath

Exclusion Criteria:

- Untreated iliac artery in-flow limiting lesion
- Significant proximal common femoral or superficial femoral artery disease above or below target lesion
- Any previously treated superficial femoral artery lesion
- Any previous stenting or surgery in the target vessel
- Femoral or popliteal aneurysm
- Non-Atherosclerotic disease resulting in occlusion (e.g. embolism, vasculitis,etc)
- Serum creatinine >2.5 mg/dl
- Any previously known coagulation disorder, including hypercoagulability
- Severe medical co-morbidities or other medical condition (for example untreated coronary heart disease and congestive heart failure, severe chronic obstructive pulmonary disease, metastasis malignance, etc.)

Primary Endpoints:

- Efficacy: Primary patency postprocedure and technical success Safety: Composite of major procedural adverse events [Time Frame: 30 Days]

Secondary Endpoints:

- Primary Patency Primary Assisted Patency Secondary Patency Clinical Success Major Amputations Target Vessel Revascularization Target Lesion Revascularization [Time Frame: 3 Months Intervals except for Target Lesion Revascularization at 12 months]

PI:

- Sarac, Timur, MD PeriTec Bioscience Ltd

PI Study Site:

- Pontificia Universidad Catolica de Chile, Santiago, Chile

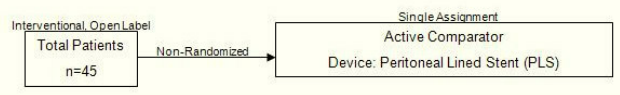
Enrollment:

- 45

Trial Start Date:

- November 2006

Trial Design:



Patient Demographics:

NOTE: P Values reported as available

This Trial is Recruiting, Patient Demographics Have Not Been Published		
Group	Result	P Value
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Results:

NOTE: P Values reported as available

This Trial is Recruiting, No Results Have Been Published		
Group	Result	P Value
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Conclusion:

- This registry is still in process and is currently targeted for a completion date of November 2010
- PeriTec is currently pursuing in human trials for the peritoneum-lined stent both in the US and internationally. For US trials this device will require an Investigational Device Exemption ("IDE"). PeriTec plans to use trial data to file for a PreMarket Approval ("PMA") with the FDA.
- The proprietary technology for PeriTec's stent system is a peritoneum material.

Last Update: June 10, 2008

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