Flexible Transseptal Puncturewire

Published: 23-06-2009
Last updated: 07-05-2024

The objective of the pilotstudy is feasibility and safety.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Cardiac arrhythmias
Study type	Interventional

Summary

ID

NL-OMON33579

Source
ToetsingOnline

Brief title
TSP

Condition

- Cardiac arrhythmias

Synonym
nvt

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: atrial fibrillation, catheter ablation, transseptal puncture

Outcome measures

Primary outcome

Success of the transseptal puncture (yes/no), duration of this part of the

procedure, and possible complications.

Secondary outcome

Technical issues that may have to be improved.

Study description

Background summary

This pilotstudy is intended to demonstrate feasibility of the new flexible puncturewire. In animal studies, this wire functioned perfectly well without any problems despite the fact the cardiologists had little experience with the anatomy of the pig that differs from humans. Production of the wire in the UMC Utrecht is standardized and destructive tests before and after ethylene oxide sterilization have shown that the connection of the tiny needle at the distal end of a standard guidewire is sufficiently strong. If the pilotstudy runs smoothly then we will apply for a larger prospective randomized study were we will compare the new and old method.

Study objective

The objective of the pilotstudy is feasibility and safety.

Study design

In 10 patients, we the feasibility and safety of a new flexible transseptal puncturewire will be investigated.

Intervention

The intervention is a slight modification of the present technique of transseptal puncture. Instead of a long stiff needle we will use a flexible guidewire with a tiny needle mounted on its distal end.

Study burden and risks

The burden for the participating patients is absent or minimal. We expect that the transseptal puncture procedure will lead to less complications and go faster.

Contacts

Public
Universitair Medisch Centrum Utrecht

Heidelberglaan 100
3584 CX
Nederland
Scientific
Universitair Medisch Centrum Utrecht

Heidelberglaan 100
3584 CX
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

All patients that have to undergo a transseptal puncture for catheter ablation of atrial fibrillation or of an accessory left sided atrio-ventricular connection.

Exclusion criteria

Patients who have undergone an earlier transseptal puncture.

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	29-10-2009
Enrollment:	10
Type:	Actual

Ethics review

Approved WMO

Date:	23-06-2009
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL22240.041.08