Evaluation of the multiplane Micro Transesophageal Echocardiographic Probe in infants.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21911

Source
NTR

Brief title
TEE Micro Probe

Health condition

Cardia Surgery
Congenital Hear Disease
Infants
TEE

Sponsors and support

Primary sponsor: Philips Ultrasound Inc.
Source(s) of monetary or material Support: Philips Ultrasound Inc.

Intervention

Outcome measures

Primary outcome

Clinical and diagnostic image quality.

Secondary outcome

N/A

Study description

Background summary

Background:

In this study we want to evaluate the clinical and diagnostic ability of the micro TEE transducer, the smallest multiplane TEE in the world, in pediatric patients greater than 2.5 kg undergoing cardiac surgery to provide data on imaging quality.

Objective:

In this study we want to evaluate the clinical and diagnostic ability of the micro TEE transducer (7.5 – 5.5 mm diameter tip, 18.5 mm length tip with a 5.2 mm diameter shaft) (Figure 1,2), the smallest multiplane TEE in the world, in pediatric patients greater than 2.5 kg undergoing cardiac surgery to provide data on imaging quality.

Design:

This study is designed as a prospective, single centre study.

Population:

The total number of patients expected to be enrolled in this trial is 42 (11). The study population consists of 40 consecutive pediatric patients greater than 2.5 kg scheduled for cardiac surgery for congenital heart disease.

Primary study parameters:

Clinical and diagnostic image quality.

Nature and extent of the burden and risks associated with participation:

No risks other than the standard risks of a TEE.

Study objective

To evaluate the clinical and diagnostic ability of the micro TEE transducer, the smallest multiplane TEE in the world, in pediatric patients greater than 2.5 kg undergoing cardiac surgery to provide data on imaging quality.

Study design

Transesophageal Echography during Cardiac Surgery.

Intervention

TEE during Congenital Heart surgery.

Contacts

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Eligibility criteria

Inclusion criteria

1. Pediatric patients with body weight > 2,5 kg;

2. Open heart surgery;

3. Congentital heart defect.

Exclusion criteria

Pediatric patients with body weight < = 2,5 kg.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	09-01-2009
Enrollment:	40
Type:	Anticipated

Ethics review

Positive opinion

Date:	07-08-2009
Application type:	First submission

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
NTR-new	NL1829
NTR-old	NTR1939
Other	MEC Erasmus MC : MEC 2009-247
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A