APD Perfusion Measurement Study

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The primary objective of this study is to test safety and performance of the APD Perfusion Measurement Catheter & Monitor for the measurement of gut perfusion in humans. The secondary objectives of this study are to assess the normal values for...

Ethical review	Not approved
Status	Will not start
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON35764

Source
ToetsingOnline

Brief title
To test safety and performance of APD devices to measure gut perfusion

Condition

- Other condition

Synonym
Blood flow in the gut. Gut mucosa perfusion

Health condition

gut perfusion

Research involving
Human

Sponsors and support

Primary sponsor: CMI GMBH
Source(s) of monetary or material Support: CMI GMBH

Intervention

Keyword: Gut perfusion, Shock

Outcome measures

Primary outcome

A device developed to determine the intestinal mucosa blood flow, measured in

ml / min

Secondary outcome

None.

Study description

Background summary

The APD Perfusion Measurement Catheter is intended to provide non-invasive measurement of gut perfusion, which can be used as an indication of septic and hypovolemic shock. The catheter also measures intra-abdomional pressure.

Study objective

The primary objective of this study is to test safety and performance of the APD Perfusion Measurement Catheter & Monitor for the measurement of gut perfusion in humans.
The secondary objectives of this study are to assess the normal values for superior mesenteric artery flow in anaesthethised surgical patients.

Study design

The APD Perfusion Measurement study is a prospective, single-center pilot study, enrolling 5 patients.
The study is to be carried out in a single centre, Zaans medisch Centrum

Study burden and risks

Prior to the procedure a Radiologist to perform transcutaneous Doppler-Echography to measure the superior mesenteric flow.
Patient is prepared for aortic vascular surgery, as per institutional

protocol. After opening of the abdomen a Gastroenterologist is to perform gastroduodenoscopy and to place the catheter.
A Doppler flow probe is placed on a branch of the mesenteric artery. The mesenteric artery flow, as measured by the Doppler flow probe and gut perfusion, as measured by the APD Catheter and Monitor are recorded for 15 minutes.
Post-procedural evaluation of the correlation between the gut perfusion, as indicated by the APD Perfusion Measurement & Monitor and the mesenteric artery flow.

The associated risks proposed in this study, are similar to risks posed by use of endoscopic and duodenal feeding procedures. These risks include bleeding, perforation and aspiration. The incident rate of perforation in gastroduodenoscopy is 0.029% for non-interventional procedures (Merchea A, et al., 2010).
The incident rates associated with the delivery and use of the APD Perfusion Measurement Catheter, are not anticipated to be greater than conventional gastro-duodenoscopic procedures. Specifically, risks to the patient are minimized due to the use of standard medical grade materials, extensive pre-clinical evaluation including in vitro bench testing and animal studies and the well established, standard nature of the endoscopic and duodenal feeding procedures used.

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

Patients for elective sugery for repair of infrarenal abdominal aneurysm

Exclusion criteria

ASA classification IV or V
Malignancy
Uncontrollable hypertension systolic > 240 mmHg or diastolic > 110 mmHg
Uncontrollable heart failure

Study design

Design

Study phase:	2
Study type:	Observational non invasive
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	5
Type:	Anticipated

Ethics review

Not approved

Date:	10-08-2012
Application type:	First submission
Review commission:	METC Noord-Holland (Alkmaar)

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	NL37183.094.11