Clinical feasibility and performance of a continuous finger blood pressure measurement device in the perioperative period

Published: 12-11-2008
Last updated: 06-05-2024

* Is the model-derived cardiac output (CO) of the Nexfin comparable to the thermodilution CO as measured by a pulmonary artery catheter (PAC) during cardiac surgery? (OBJECTIVE I)* Does the Nexfin reliably measure changes in stroke volume variation…

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON32532

Source
ToetsingOnline

Brief title
Nexfin study

Condition

- Other condition

Synonym
Hemodynamic alterations in the perioperative period

Health condition

Hemodynamiek in de perioperatieve periode

Research involving

Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W,De Nexfin is verkregen middels een subsidie van het ICaR-VU

Intervention

Keyword: Continuous blood pressure measurements, Hemodynamics, Postoperative complications, Pulse pressure variation

Outcome measures

Primary outcome

* Correlation between cardiac output (CO) derived from thermodilution method

and CO as calculated by Nexfin (Objective I)

* Pressure drop during Valsalva maneuver of 20 mmHg (Objective II).

* PPV drop of 7.5% due to fluid redistribution in the postoperative period as

compared to the preoperative PPV (Objective III)

Secondary outcome

* Pulse pressure variation (PPV): The percentage change of the pulse pressure

during the breathing/respiratory ventilation cycle.

* Continuous blood pressure (CBP)

* Stroke volume variation (SVV): The percentage change between the maximal and

minimal stroke volumes (SV) divided by the average of the minimum and maximum

over a floating period of 30 seconds.

* Fluid balance

* Demographic patient variables: age, sex, weight, length, comorbidities.

* Surgical patient variables: fluid therapy, number of blood transfusions

Study description

Background summary

The department of Anesthesiology of the VUmc recently started to focus on postoperative hemodynamic monitoring in surgical patients who have no arterial entrance and are not ventilated. In order to do so, a continuous blood pressure measurement device (Nexfin) should be validated in order to define its value in this postoperative monitoring of patient hemodynamics. In the present study we therefore aim to evaluate the clinical feasibility and performance of the Nexfin device in the intraoperative and postoperative phase in healthy volunteers and surgical patients.

Study objective

* Is the model-derived cardiac output (CO) of the Nexfin comparable to the thermodilution CO as measured by a pulmonary artery catheter (PAC) during cardiac surgery? (OBJECTIVE I)
* Does the Nexfin reliably measure changes in stroke volume variation (SVV) and pulse pressure variation (PPV) as induced by validated tests in healthy volunteers? (OBJECTIVE II)
* Are SVV and PPV measurements of value in surgical patients when used for the detection of perioperative and postoperative changes in system hemodynamics? (OBJECTIVE III)

Study design

Open, prospective, observational trial
The study will be performed in the VU University Medical Center
Inclusion of healthy volunteers or patients undergoing cardiothoracic or abdominal surgery

Study burden and risks

Nexfin device
Continuous blood pressure measurements will be performed by placing a finger cuff around the middle index of the dominant hand. The hand will be placed in a comfortable position when the patient or volunteer is in a supine position. This technique is associated with minimal discomfort for the patient.
Perioperative measurements
Except for the blood pressure measurement in the 30 minutes before anesthesia induction, all intraoperative Nexfin measurements will be performed under anesthesia. All anesthesia and surgery procedures will be performed as usual. Discomfort due to intraoperative Nexfin measurements is regarded as minimal.
Valsalva maneuver

The Valsalva maneuver can be performed by forcibly exhaling against a closed glottis (a closed airway), for instance to detect an inguinal hernia or to clear the ears during diving. In the present study, volunteers and patients will perform a Valsalva maneuver by blowing into a manometer-controlled device that allows standardization of the pressure which induces the Valsalva effects. This measurement is associated with minimal discomfort. Since the pressure may induce pain around the incision wound, pressure will be adapted to patient comfort.
Controlled breathing
Volunteers and patients will perform a cycle of metronome-controlled breathing to mimic ventilation conditions. This is regarded to induce minimal discomfort.
Quick Standing test
Volunteers and patients are asked to quickly change from supine to standing position. Standing is part of the revalidation program in surgical patients. However, patients who are unable to stand are excluded from this test.

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

Group A (Patients undergoing cardiothoracic surgery)
* Patients undergoing elective cardiothoracic surgery
* Use of a pulmonary artery catheter (PAC)
* Age 18-75 years
* Maximal ICU stay of 24 hours
* Informed consent
Group B (Volunteers)
* Males
* Healthy subjects
* Age 18-50 years
* Informed consent
Group C (Patients undergoing elective abdominal surgery)
* Patients undergoing elective abdominal surgery
* Age 18-75 years
* Informed consent

Exclusion criteria

Group A (Patients undergoing cardiothoracic surgery)
* Emergency operation
* Body mass index (BMI) 15 < BSA > 35
* Diabetes mellitus
Group B (Volunteers)
* Body mass index (BMI) 15 < BSA > 35
* Underlying cardiovascular diseases
* Use of beta blockers or anti-hypertensive drugs
* Use of diuretics
* Diabetes mellitus
* Use of coffee or cigarettes before the measurements take place
Group C (Patients undergoing elective abdominal surgery)
* Body mass index (BMI) 15 < BSA > 35
* Use of beta blockers or anti-hypertensive drugs
* Use of diuretics
* Diabetes mellitus

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	10-12-2008
Enrollment:	111
Type:	Actual

Ethics review

Approved WMO

Date:	12-11-2008
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL24515.029.08