

Value of Nexfin SVV and PPV to predict fluid responsiveness during anaesthesia

Submission date 26/07/2012	Recruitment status Stopped	☐ Prospectively registered ☐ Protocol
Registration date 16/08/2012	Overall study status Stopped	☐ Statistical analysis plan ☐ Results
Last Edited 09/11/2015	Condition category Surgery	☐ Individual participant data ☐ Record updated in last year

Plain English summary of protocol

Background and study aims

Patients undergoing surgery often require fluids to be infused into their veins to compensate for blood loss. However, giving patients fluids is only beneficial if it increases the volume of blood pumped by the heart, but this 'fluid responsiveness' varies depending on the patient's blood volume. This is mostly assessed using invasive techniques, so current practice does not include this assessment in most patients under anesthetic. The Nexfin monitor uses a non-invasive finger cuff to assess blood parameters and can be used in all patients under general anesthetic. The aim of this study is to assess the value of using the Nexfin monitor to predict the fluid responsiveness of patients under anesthetic.

Who can participate?

Patients aged over 18 undergoing surgery under general anesthetic.

What does the study involve?

During normal routine clinical practice, we record the patients' hemodynamic parameters (e.g., blood pressure, volume of blood pumped by the heart, heart rate) using the Nexfin monitor during procedures where fluid administration was required. We evaluate the changes in these parameters during fluid administration and their value in predicting the patients' fluid responsiveness.

What are the possible benefits and risks of participating?

There are no benefits or risks involved.

Where is the study run from?

University Medical Center Groningen (Netherlands).

When is the study starting and how long is it expected to run for?

November 2011 to August 2012.

Who is funding the study?

Investigator initiated and funded

Who is the main contact?

Dr Alain Kalmar

Contact information

Type(s)

Scientific

Contact name

Dr Alain Kalmar

Contact details

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Additional identifiers

Protocol serial number

vol-001

Study information

Scientific Title

Value of Nexfin SVV and PPV to predict fluid responsiveness during anaesthesia

Study objectives

The dynamic preload variables (SSV and PPV) assessed by Nexfin, are better predictors to assess fluid responsiveness than blood pressure or heart rate

Ethics approval required

Old ethics approval format

Ethics approval(s)

Medisch Ethische Toetsingscommissie (METc), Universitair Medisch Centrum Groningen, 19/04/012, ref: metc2012/107

Study design

Retrospective data analysis

Primary study design

Observational

Study type(s)

Other

Health condition(s) or problem(s) studied

Anaesthesia

Interventions

N/A

Intervention Type

Procedure/Surgery

Phase

Not Applicable

Primary outcome(s)

We will evaluate the evolution of hemodynamic parameters during the period of fluid administration and the value of the dynamic preload-variables to predict fluid responsiveness

Key secondary outcome(s)

No secondary outcome measures

Completion date

08/08/2012

Reason abandoned (if study stopped)

Objectives no longer viable

Eligibility

Key inclusion criteria

>18 years

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

Unable or unwilling to grant written informed consent for data analysis

Date of first enrolment

01/11/2011

Date of final enrolment

08/08/2012

Locations

Countries of recruitment

Netherlands

Study participating centre

University Medical Center Groningen

Groningen

Netherlands

9700 RB

Sponsor information

Organisation

University Medical Center Groningen (Netherlands)

ROR

<https://ror.org/03cv38k47>

Funder(s)

Funder type

Other

Funder Name

Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan**IPD sharing plan summary**

Not provided at time of registration