

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

Submission date 26/07/2012	Recruitment status Stopped	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 16/08/2012	Overall study status Stopped	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 09/11/2015	Condition category Surgery	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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

University Medical Center Groningen

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Cross sectional study

Study setting(s)

Hospital

Study type(s)

Other

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Anaesthesia

Interventions

N/A

Intervention Type

Procedure/Surgery

Phase

Not Applicable

Primary outcome measure

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

Secondary outcome measures

No secondary outcome measures

Overall study start date

01/11/2011

Completion date

08/08/2012

Reason abandoned (if study stopped)

Objectives no longer viable

Eligibility

Key inclusion criteria

>18 years

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

80

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)

Sponsor details

Hanzeplein 1

PO Box 30001

Groningen

Netherlands

9700 RB

Sponsor type

Hospital/treatment centre

Website

<http://www.umcg.nl/>

ROR

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

Funder(s)

Funder type

Other

Funder Name

Investigator initiated and funded

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration