Nexfin monitoring and laboratory testing in the per-and postoperative setting of major hepatectomy

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

Summary

ID

NL-OMON41251

Source
ToetsingOnline

Brief title
NeMo study

Condition

- Other condition
- Hepatic and hepatobiliary disorders

Synonym
decompensatio cordis, overvulling

Health condition

Vochthouding in het lichaam tijdens en na een leverresectie

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Fluid overload, Hemodynamics, Neurohumoral response, Non-invasive monitoring

Outcome measures

Primary outcome

Preoperative

* Weight

* Nexfin parameters: Stroke volume, cardiac output and cardiac index

* 2x 24-hours urine sample for sodium, potassium and creatine excretion

* 1x plasma sample antidiuretic hormone, aldosterone and renin

Intraoperative

* Fluid responsiveness after 250 ml fluid administration

* Nexfin monitoring

* Fluid balance and amount of fluids administered (ml.kg-1.h-1)

Postoperative

* 3 times a day Nexfin parameters: Stroke Volume, Cardiac Output and Cardiac

index. The first measurement is in the morning before mobilization and after 2

minutes mobilization (out of bed; standing of sitting on a chair).

* Daily body weight and ankle & abdominal girth

* 2x 24-hour urine sample with sodium, potassium and creatine excretion

* First 5 days at the ward: daily measurement of electrolytes sodium,

potassium, bicarbonate and chloride.

* Daily measurements of plasma concentrations aldosterone, renin and

antidiuretic hormone will be done before mobilization and after 20 minutes

mobilization.

Secondary outcome

nvt

Study description

Background summary

In 2011, thirty-four major liver resections (resection *3 segments) were performed in the AMC. The outcome of these hemihepatectomies has improved in the last years because of better surgical techniques and postoperative care. Nevertheless, there is a large amount of patients who will develop fluid overload postoperatively.

The stress response to surgery causes anti-diuresis and oliguria. Fluid administration seems to be a logical step in case of decreased diuresis. However, after trying to control hypotension with fluid admission, a large amount of patients develop fluid overload, with the following symptoms: weight gain, delayed intestinal motility, pleural effusion, ascites and extended hospital stay.
Therefore, this raises the question whether a decreased diuresis is a consequence of hypovolemia, which can be controlled by intravenous fluid administration.
To answer this question we need a more extensive device (in addition to standard monitoring of blood pressure, heart rate and oxygen saturation) to monitor the hemodynamic state of the patient per- and post-operatively. We will use the Nexfin to retrieve supplemental parameters to get a better idea of the cardiovascular state of the patient. The parameters will be cardiac output, cardiac index and stroke volume.

Study objective

The aim of this study is to retrieve extra measurements by Nexfin and laboratory testing in the per- and postoperative period. Can the use of Nexfin contribute in the generation of meaningful data to get an idea of the hemodynamic state of the patient during and after surgery?

Study design

15 patients undergoing a major liver resection, will be monitored with the Nexfin monitor per- and postoperatively. At admission, we will measure the cardiac output, cardiac index and stroke volume to get a baseline value. During the operation, every hour a 250 ml fluid challenge will indicate fluid responsiveness, measured by Nexfin.
Postoperatively, patients will be measured by Nexfin two times a day. The urine concentrations of sodium, potassium and creatine in a 24-hours urine sample will be measured twice during hospital stay. Furthermore plasma samples of aldosterone, renin and ADH will be taken pre and postoperatively. The patients will receive the standard care. No intervention will be done based on the Nexfin results.

Study burden and risks

The risks of participating in this trial are low. No extra interventions are performed, only the Nexfin finger cuff is wrapped around the finger and no complications of this finger cuff have been reported. The 24-hour urine collections, plasma samples and nexfin baseline measurements before the operation can be collected during the standard outpatient clinic visits.
The potential benefits of this study are substantial. The proposed study aims to do this in a minimally invasive setting that will impose no significant burden on patients participating in this study.

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 who will undergo a major hepatectomy

Exclusion criteria

cirrhosis, renal failure, cardiac failure and cardiac arrythmias

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):	03-10-2013
Enrollment:	15
Type:	Actual

Medical products/devices used

Generic name:	Nexfin
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	12-04-2013
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

ID: 20404
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL43476.018.13
OMON	NL-OMON20404