Nexfin monitoring and laboratory testing during and after a liver resection

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON20404

Source
Nationaal Trial Register

Brief title
NEMO

Sponsors and support

Primary sponsor: Academic Medical Center Amsterdam
Source(s) of monetary or material Support: Academic Medical Center, Amsterdam

Intervention

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 aldosterone, renin and antidiuretic hormone

Intra-operative:

- Fluid responsiveness, expressed by a rise ≥ 20 units in stroke volume

- Blood pressure

- 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

- 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 of mobilization.

Secondary outcome

- Weight gain during postoperative period (max delta kg)

- Duration of hospital stay

- Complications

- Reproducibility

Study description

Background summary

Rationale:

The only curative treatment for malignant liver tumors is a partial liver resection. Many patients develop postoperative complications due to fluid overload, such as cardiovascular events and renal failure, which increase the length of hospital stay. Unfortunately, the pathophysiology of fluid overload in these patients remains unknown as well as an optimal strategy for fluid management perioperatively.

Objective:

The aim of this study is to retrieve extra measurements by Nexfin and laboratory testing in the per- and postoperative period. These measurements will give us a better understanding of the hemodynamic state of the patient.

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.

Study population:

Patients who are 18-80 years old, undergoing major hepatic resection, able and willing to participate, will be included.
Patients with renal and cardiac failure will be excluded, as well as patients who develop sepsis in the postoperative period.

Intervention:

No intervention will be done. Patients will receive the standard therapy following ‘Zorgpad leverresecties.

Main study parameters/endpoints:

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, expressed by a rise ≥ 20 units in stroke volume

- Blood pressure

- 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.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness

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.

Study objective

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 design

Preoperatively

- Weight,

- Nexfin measurements: cardiac output, cardiac index and stroke volume.

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

- plasma ADH, renin and aldosterone

Intra operative:

- Fluid responsiveness after 250 ml fluid administration

- Nexfin monitoring

- Fluid balance

Post operative

- 3 times a day measurement with Nexfin: Cardiac output, stroke volume and cardiac index

- Daily body weight, ankele and abdominal girth

- 2x24H urine sample with sodium, potassium and creatine excretion

- 5 days postop: daily measurements of electrolytes and ADH, renin and aldosterone.

Intervention

No interventions will be done. Only measurements with the medical device Nexfin.

Contacts

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Eligibility criteria

Inclusion criteria

- Patients (18 years or older) who will undergo a major hepatectomy (≥3 segments) and who

signed informed consent.

- Patient with ASA classification I and II.

Exclusion criteria

- Age < 18 and > 85 years

- Renal failure (Estimated GFR < 30 ml/min using the Modification of Diet in Renal Disease formula MDRD)

- Cardiac failure (LVEF <30%)

- Cardiac arrhythmias

- Liver cirrhosis

- Admission on intensive care unit postoperatively

- Severe sepsis

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non controlled trial

Control: N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-07-2013
Enrollment:	15
Type:	Anticipated

Ethics review

Positive opinion
Date: 04-06-2013
Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 41251
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL3860
NTR-old	NTR4020
CCMO	NL43476.018.13
ISRCTN	ISRCT wordt niet meer aangevraagd.
OMON	NL-OMON41251

Study results

Summary results
N/A