

Optimalisation of fluid balance with Flowtrac/Vigileo during the HIPEC procedure

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Goal is to use two non-invasive techniques (continuous cardiac output monitoring and impedance measurement) to investigate the possibility of cardiac output measurement and impedance measurement to reduce the fluid intake with 30% reduction while...

Ethical review	Not approved
Status	Will not start
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON36111

Source

ToetsingOnline

Brief title

Optifluid

Condition

- Other condition
- Malignant and unspecified neoplasms gastrointestinal NEC

Synonym

bowel cancer, carcinomatosis peritonei

Health condition

circulatie

Research involving

Human

Sponsors and support

Primary sponsor: Sint Antonius Ziekenhuis

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Flowtrac/Vigileo, fluid balance, hemodynamic monitoring, HIPEC

Outcome measures

Primary outcome

Reducing positive fluid balance 30%. Differences in plasma electrolytes and differences in measured responses inflammatoire including cytokines and CRP.

Secondary outcome

Secondary endpoints: use of inotropes and diuretics, observation of occurrence of complications, duration of mechanical ventilation and ICU stay.

Study description

Background summary

Previous research has shown that liberal perioperative hydration can lead to an increase in wound healing disorders and ischemic changes with edema and greater risk of anastomotic leakage. It is likely that a liberal perioperative fluid policy also contributes to these postoperative complications.

During HIPEC postoperative inflammatory responses exist induced by the surgery itself, the surgical trauma and chemical trauma of chemotherapy. This response is often accompanied by increased fluid requirements. In this study, both the monitored fluid requirements and administration as well as the inflammatory response are part of this observational study.

Study objective

Goal is to use two non-invasive techniques (continuous cardiac output monitoring and impedance measurement) to investigate the possibility of cardiac output measurement and impedance measurement to reduce the fluid intake with 30% reduction while maintaining normal hemodynamics. The question is whether

this more restrictive fluid policy also affects the inflammatory response.

Study design

In total, 32 patients are included. we will use a web-based program to randomize between a policy with standard monitoring and fluid replacements or with continuous noninvasive cardiac output measurement and impedance measurement adapted "restrictive" fluid policy.

Study burden and risks

To non-invasive cardiac output monitoring is no additional risk than the risks of placing a central venous line and arterial line. These forms of surveillance are standard hemodynamic monitoring for a HIPEC procedure.

The advantage is that patients may have a shorter hospital stay in the ICU, less diuretic use and a lower risk of wound healing problems or anastomotic leaks.

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

age > 18 years

carcinomatosis peritonei

Hipec procedure

Exclusion criteria

no sinusrhythm (No validity of Flowtrac)

Left ventricle dysfunction (severe LVEF < 40%)

severe coronary artery disease

Suboptimal macroscopic debulking and aborting the HIPEC procedure

preoperative diuretic use

Study design

Design

Study type: Observational non invasive

Intervention model: Parallel

Allocation: Randomized controlled trial

Masking: Open (masking not used)

Primary purpose: Prevention

Recruitment

NL

Recruitment status: Will not start

Enrollment: 32

Type: Anticipated

Medical products/devices used

Generic name: Flowtrac/Vigileo
Registration: Yes - CE intended use

Ethics review

Not approved
Date: 07-04-2011
Application type: First submission
Review commission: MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL36185.100.11