# **Optimalisation of fluid balance with Flowtrac/Vigileo during HIPEC procedures**

Published: 14-02-2011 Last updated: 04-05-2024

reduction of fluid administration of 30%

Ethical review	Not approved
Status	Will not start
Health condition type	Miscellaneous and site unspecified neoplasms malignant and unspecified
Study type	Interventional

# Summary

### ID

NL-OMON34425

**Source** ToetsingOnline

**Brief title** Optifluid

# Condition

• Miscellaneous and site unspecified neoplasms malignant and unspecified

### Synonym

peritonitis carcinomatosa, tumors

#### **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, Fluid balance, HIPEC procedure, inflammation

1 - Optimalisation of fluid balance with Flowtrac/Vigileo during HIPEC procedures 13-05-2025

### **Outcome measures**

#### **Primary outcome**

Reduction of fluid by 30 %

#### Secondary outcome

ICU stay

number of days of mechanical ventilation

use of diuretics postoperative

measurement of inflammation

# **Study description**

#### **Background summary**

Large amounts of fluid administration leads to more complications and longer ICU stay after laparotomy. Use of a device like the Flowtrac/vigileo can reduce the amounts of fluid in order to reduce complication rate and ICU stay.

#### **Study objective**

reduction of fluid administration of 30%

#### Study design

Two groups of 12 patients will be randomized between standard monitoring or additive monitoring with flowtrac/Vigileo and pulsed dye densitometrie. Furthermore a few blood samples will be drawn in order to study the inflammation effect of HIPEC procedures. Theoretically also the use of postoperative diuretic use should be reduced

#### Intervention

Extensive monitoring with flow trac vigileo and pulsed dye densitrometry blood sampling to measure the inflammation proces

#### Study burden and risks

a few bloodsamples will be drawn (4 ml)

# Contacts

**Public** Sint Antonius Ziekenhuis

Koekoekslaan 1 3430 EM Nieuwegein Nederland **Scientific** Sint Antonius Ziekenhuis

Koekoekslaan 1 3430 EM Nieuwegein Nederland

# **Trial sites**

### **Listed location countries**

Netherlands

# **Eligibility criteria**

#### Age

Adults (18-64 years) Elderly (65 years and older)

### **Inclusion criteria**

HIPEC procedure age 18 years and older

# **Exclusion criteria**

cardiac aritmia LVEF < 40%

3 - Optimalisation of fluid balance with Flowtrac/Vigileo during HIPEC procedures 13-05-2025

severe coronary artery disease not possible to do an optimal debulking use of diuretics preoperatively

# Study design

# Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Prevention

# Recruitment

NL	
Recruitment status:	Will not start
Enrollment:	24
Туре:	Anticipated

### Medical products/devices used

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

# **Ethics review**

Not approved	
Date:	14-02-2011
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 CCMO ID NL33966.100.10