Hemodynamic monitoring during HIPEC procedures

No registrations found.

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

Summary

ID

NL-OMON21344

Source
Nationaal Trial Register

Brief title
HEMOHIP- studie

Health condition

invasive hemodynamic monitoring has more complications compared to non invasive monitoring. However invasive monitoring is better compared to less invasive monitoring. Can less invasive monitroring devices be used during these procedure.
hemodynamic monitoring
SIRS
surgery

Sponsors and support

Primary sponsor: Radboudumc
Afdeling anesthesiologie, pijn en palliatieve geneeskunde
postbus 9101
6500 HB NIJMEGEN
Source(s) of monetary or material Support: non

Intervention

Outcome measures

Primary outcome

Determining the reliability of the less invasive hemodynamic measurement methods with respect to the reference measuring method (= TPTD), for a variety of pre-defined moments peri and post OK.

Comparison absolute numbers; TPTD vs less invasive Cardiac Output (bias, precision, limits of agreement, percentage of error; Bland Altman plot). By time (T1 ... .T9), and all paired data points corrected for "repeated measurements".

Secondary outcome

ROC curve to detect SV change > 15%

Study description

Study objective

Non invasive hemodynamic monitoring is as good as invasive monitoring

Study design

T = 0, synchronization clocks, calibrate CCO PiCCO using TPTD,

T2 and T3 measurement in the middle of debulking period;

T4 start HIPEC;

T5 middle HIPEC;

T6 end HIPEC;

T7 end OK;

T8 and T9 on the IC around 6 and 12 hours post operative

Intervention

Comparison:

invasive hemodynamic monitoring (PICCO) vs less invasive monitoring (ProaQt and FloTrac)

and non invasive monitoring (nexfin/clearsight)

Contacts

Public
Radboudumc

Cor Slagt
Nijmegen
The Netherlands
Scientific
Radboudumc

Cor Slagt
Nijmegen
The Netherlands

Eligibility criteria

Inclusion criteria

Patients undergoing a HIPEC procedure and receive hemodynamic monitoring with the TPTD through PiCCO monitoring.

Patients older than 18 years

Exclusion criteria

- Severe tricupid or aortic regurgitation

- Severe peripheral vascular dissease

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Other
Start date (anticipated):	01-11-2015
Enrollment:	25
Type:	Unknown

Ethics review

Positive opinion

Date:	11-06-2015
Application type:	First submission

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
NTR-new	NL5117
NTR-old	NTR5249

Register	ID
Other	CMO Regio Arnhem-Nijmegen : 2015-1793

Study results