Effect of new technology on the behaviour of clinicians regarding the treatment of hypotension during surgery

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Does education intervention about adding HPI to standard practice alter clinician behaviour to the treatment of hypotension? As a secondary objective we assess whether incorporating HPI in a Goal-directed fluid therapy (GDFT) algorithm lowers the...

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON27636

Bron
Nationaal Trial Register

Verkorte titel
HypoIQ

Aandoening

Anesthesiology
Hypotension

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

A range of social-cognitive determinants of behaviour change including attitudes, self-efficacy, social norms, skills, as well as factors relating to the normalisation of technology into routine practice through qualitative data analysis.

Toelichting onderzoek

Achtergrond van het onderzoek

Intraoperative hypotension has a high incidence in the perioperative population and is associated with an increase in postoperative complications and mortality. A MAP below 65 mmHg or a decrease of ƒ®20% from baseline increases the incidence of myocardial injury after non-cardiac surgery (MINS) and acute kidney injury (AKI). Recently, the FloTrac IQ algorithm (Edwards Lifesciences, Irvine, CA, USA) incorporating a hypotension predictability index (HPI), dynamic arterial elastance variable (Eadyn) and index assessment of left ventricular contractility (dP/dT) was developed which provides clinicians an early warning of an impending hypotensive episode as well as insight into its pathophysiology and thus buys time to take measures to prevent this hypotension from occurring. In addition, this algorithm also incorporates variables used in standard care such as pulse pressure variation (PPV), stroke volume variation and index (SVV and SVI) and cardiac index (CI). Whether clinicians find the new information acceptable to use, or that it confers clinical utility remains unknown and for this technology to become accepted, and in turn lead to a reduced incidence of hypotension, this would require a change in current behaviours including attitudes and skills. The underlying rationale is that by using the HPI and secondary information, intraoperative hypotension can be reduced and appropriately treated or even prevented. Alternatively, hypotension can also be avoided simply by requiring the treating clinician to keep the MAP >65 mmHg, although the treatments may be inappropriate in view of the underlying pathophysiology. Therefore, we aim to use education intervention on treatment of hypotension and incorporating HPI in this clinical treatment to alter clinician¡¦s behaviour.

Doel van het onderzoek

Does education intervention about adding HPI to standard practice alter clinician behaviour to the treatment of hypotension?

As a secondary objective we assess whether incorporating HPI in a Goal-directed fluid therapy (GDFT) algorithm lowers the incidence of intraoperative hypotension.

Onderzoeksopzet

- after cohort 1, before education: structured inteview about beliefs of clinicians (15-20) about costs and benefits of controlling hypertension.

- During cohort 2 and 3: questionnaires for clinicians attending cohort 2 and 3 about the perceived barriers for effective control of hypotension.

- 2 motnhs after training FlowTracIQ: questionnaires about usefulness en usibility of the FlowTracIQ and observations of 6-8 surgical procedures

- After phase 3; workshop with other clinicians focusing on likelihood of wider adoption.

Onderzoeksproduct en/of interventie

Patients:

Cohort 1 (first 50 patients): management of hypotension as usual.

Cohort 2 (second 50 patients): management of hypotension keeping the MAP >65.

Cohort 3 (third 50 patients): management of hypotonsion by using the FlowTrac IQ

Clinicians:

Between cohort 1 and 2, treating physicians receive education intervention regarding current evidence of intraoperative hypotension and adverse outcomes. Between cohort 2 and 3, treating physicians receive education intervention regarding how to use FlowTrac IQ and its parameters in the clinical management of hypotension.

On various time points, interviews and questionnaires measuring a range of social-cognitive determinants of behavior change will be performed.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

• Patients due to undergo elective major abdominal, orthopedic, head and neck or vascular surgery requiring invasive arterial monitoring (decided at the discretion of the treating clinician) under general anesthesia with positive pressure ventilation, and with an expected duration of greater than 90 minutes, who will have goal directed fluid therapy performed as part of their standard care.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

• Requirement for an intentional intraoperative MAP of less than 65 mmHg as decided by the treating surgeon and/or anesthetist.

• A preoperative MAP of lower than 65 mmHg documented on 2 separate occasions at preoperative assessment clinic.

• Patients with significant right or left ventricular failure

• Patients with known intra cardiac shunt.

• Patients with known severe aortic stenosis (peak velocity greater than 4 meter per second and/or aortic valve area less than 1 cm2)

• Patients with known cardiac arrhythmias

• Planned positive pressure ventilation with tidal volume < 7 ml/kg

• Patients undergoing hepatic surgery

• Patients requiring dialysis.

• Patients who do not have the capacity to consent

• Patients aged less than 18 years of age.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Niet-gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-07-2018
Aantal proefpersonen:	150
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL7091
NTR-old	NTR7289
Ander register	Research Register UMCG : 201800452

Resultaten