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Hemodynamic stability and tissue oxygenation during balanced propofol remifentanil-based anaesthesia with high level of analgesia

Submission date 19/06/2012	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 13/07/2012	**Overall study status** Completed	
Last Edited 17/12/2020	**Condition category** Surgery	

Plain English summary of protocol

Background and study aims
On some occasions, general anesthetic with a high antinociceptive (pain-blocking) effect is required although it might cause hypotension (low blood pressure). The aim of this study is to investigate whether a high-antinociceptive general anesthetic, together with fluids and norepinephrine, results in preservation of tissue oxygen levels and cardiac (heart) output.

Who can participate?
Patients aged over 18 scheduled to receive general anesthetic for surgery that requires a high level of antinociception

What does the study involve?
General anesthetic is administered following normal clinical practice guidelines, during which tissue oxygen levels and cardiac output are measured non-invasively.

What are the possible benefits and risks of participating?
There are no benefits or risks for participants because it is an observational study and normal clinical practice guidelines are followed.

Where is the study run from?
University Medical Center Groningen (Netherlands)

When is the study starting and how long is it expected to run for?
May 2011 to July 2011

Who is funding the study?
University Medical Center Groningen (Netherlands)

Who is the main contact?
Dr Alain Kalmar

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
CM-01

Study information

Scientific Title
Hemodynamic stability and tissue oxygenation during balanced propofol remifentanil-based anaesthesia with high level of analgesia: an observational study

Study objectives
A propofol/remifentanil based anesthesia with high stability against intermittent noxious stimuli requires a relatively low level of propofol and a relatively high level of remifentanil to preserve an adequate aneaesthesia, as described by Bouillon. This combination may induce hypotension which can be treated by fluid administration and norepinephrine. Specifically administration of norepinephrine may be controversial in the light of tissue oxygenation and stroke volume. This study investigates whether a moderate administration of norepinephrine, combined with adequate fluid therapy results in preserved cardiac output and tissue oxygenation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Medical Ethical Committee (METC), University Medical Center Groningen [Medisch Ethische Toetsingscommissie, Universitair Medisch Centrum Groningen], 15/04/2011, ref 2011.052

Study design

Single-center observational study

Primary study design
Observational

Secondary study design
Other

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Tissue oxygenation and hemodymanics in anesthesia

Interventions
Administration of norepinephrine following good clinical practice.

Intervention Type
Procedure/Surgery

Phase
Not Applicable

Primary outcome measure
1. Tissue oxygenation, measured continuously and non-invasively using the InSpectra StO2 monitor (Hutchinson Technology, Hutchinson, USA)
2. Cardiac output, measured using Nexfin (BMEye, Amsterdam, Netherlands)

Secondary outcome measures
Time to extubation calculated by measuring the time interval between stopping of the syringes and the moment at which the patient is extubated

Overall study start date
01/05/2011

Completion date
31/07/2011

Eligibility

Key inclusion criteria
1. Age >18 years
2. Patients planned for ophtalmic surgery under general anesthesia

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
40

Total final enrolment
40

Key exclusion criteria
1. Unwilling/unable to written informed consent
2. Neuropsychiatric history

Date of first enrolment
01/05/2011

Date of final enrolment
31/07/2011

Locations

Countries of recruitment
Netherlands

Study participating centre
University Medical Center Groningen
Groningen
Netherlands
9700RB

Sponsor information

Organisation
University Medical Center Groningen (UMCG) (Netherlands)

Sponsor details

Hanzeplein 1
PO Box 30 001
Groningen
Netherlands
9700RB

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/03cv38k47

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Universitair Medisch Centrum Groningen

Alternative Name(s)
University Medical Center Groningen, UMCG

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Netherlands

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	30/10/2014	17/12/2020	Yes	No