

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

<b>Submission date</b> 19/06/2012	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 13/07/2012	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 17/12/2020	<b>Condition category</b> Surgery	<input type="checkbox"/> Individual participant data

## 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

Dr Alain Kalmar

## Contact details

University Medical Center Groningen  
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PO Box 30 001  
Groningen  
Netherlands  
9700RB

# 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 anaesthesia, 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 hemodynamics 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 StO<sub>2</sub> 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?
<a href="#">Results article</a>	results	30/10/2014	17/12/2020	Yes	No