

# Assessment of Capnography in Monitoring Patients during Deep Sedation with Propofol

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At the Centre for Contraception, Sexuality and Abortion Leiden, abortion procedures are performed under deep sedation using Propofol. Patient\*s monitoring is performed by nurses qualified in patient sedation management, using pulse oximetry and...

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Other condition
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON35334

### Source

ToetsingOnline

### Brief title

Capnography during deep sedation

### Condition

- Other condition
- Abortions and stillbirth

### Synonym

alveolar hypoventilation, oxygen debt

### Health condition

iatrogeen veroorzaakte hypoventilatie door sedatie

### Research involving

Human

## Sponsors and support

**Primary sponsor:** Centra voor Anticonceptie, Seksualiteit en Abortus CASA

**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** capnography, deep sedation, monitoring, respiratory complications

## Outcome measures

### Primary outcome

The primary outcome for both groups is the number of patients with oxygen saturations to  $\leq 90\%$  (minor hypoxemia), as measured by continuous pulse oximetry.

### Secondary outcome

Secondary study outcomes are the number of patients with saturations to  $\leq 80\%$  (major hypoxemia), dose of administered propofol, problems during the abortion procedure, airway interventions, early termination of the procedure due to respiratory problems, episodes of bradycardia, and administration of atropine.

## Study description

### Background summary

The current standard of care for patients during deep sedation is continuous pulse oximetry with visual assessment of the patient. Clinical research has demonstrated that hypoxemia secondary to depressed respiratory activity is a principal risk factor during sedation. Capnography may provide early detection of alveolar hypoventilation before hypoxemia has occurred in nonintubated patients and thereby improve patient safety during sedation.

### Study objective

At the Centre for Contraception, Sexuality and Abortion Leiden, abortion procedures are performed under deep sedation using Propofol. Patient\*s

monitoring is performed by nurses qualified in patient sedation management, using pulse oximetry and their clinical judgement. The aim of this study is to examine the effectiveness of microstream capnography in early detection of alveolar hypoventilation during deep sedation in compare to standard monitoring with pulse oximetry in abortion procedures.

## **Study design**

The protocol contains a prospective, open, randomized controlled trial with two study arms. All patients receive standard care of monitoring performed by the medical staff. The randomized trial examines whether capnography prevents patients from having respiratory events during deep sedation in abortion procedures. Patients randomized in the control group receive standard of care using pulse oximetry. In the intervention arm, respiratory monitoring is performed with pulse oximetry and capnography. Before the trial starts, all nurses qualified in patient sedation management and abortion doctors will be trained in assessment of capnography. The nurses qualified in patient sedation management then interpret the capnographic signal. If signals are indicating alveolar hypoventilation, the medical staff can anticipate.

## **Intervention**

The intervention comprises application of capnography during deep sedation with propofol. In the intervention arm, patients\* breathing is additionally monitored with capnography. If alveolar hypoventilation is detected medical staff can intervene by arousing the patient, performing chin lift, repositioning the head, provision of oxygen, or abandon from giving additional propofol. These interventions represent the standard of care currently used by the clinical staff to respond to hypoventilation and hypoxemia.

## **Study burden and risks**

The risks related to the conduct of this study are negligible and the burden minimal. Patients in both groups receive the current standard of care. Patients randomized in the intervention group would get benefit form the addition of capnography to the monitoring by early detection of alveolar hypoventilation. Patients are charged with a single questionnaire before the survey. Capnography is a noninvasive measurement by means of a cannula under the nose, which before the sedation may tickle, but during sedation no inconvenience is expected.

## **Contacts**

### **Public**

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## **Trial sites**

### **Listed location countries**

Netherlands

## **Eligibility criteria**

### **Age**

Adults (18-64 years)

Elderly (65 years and older)

### **Inclusion criteria**

Age 18 years or older

Abortion procedures performed until 22 weeks of gestational age

American Society of Anaesthesiologists (ASA) classes I to II (normal healthy patients or patients with a mild systemic disease)

Ability to give written informed consent.

### **Exclusion criteria**

Inability to provide written informed consent

History of allergic reactions to propofol, soybeans or egg proteins

American Society of Anaesthesiologists (ASA) classes III to V (patients with a severe systemic disease, with or without constant threat to life, or moribund patients)

Sleep apnea syndrome

Patients with known seizure disorders

## Study design

### Design

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

**Primary purpose:** Diagnostic

### Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	21-04-2010
Enrollment:	440
Type:	Actual

### Medical products/devices used

Generic name:	Capnograph
Registration:	Yes - CE intended use

## Ethics review

Approved WMO	
Date:	25-03-2010
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

## 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
CCMO	NL29266.041.09