Assessment of Capnography in Monitoring Patients during Deep Sedation with Propofol

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	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 <=90% (minor hypoxemia), as measured by continuous pulse oximetry.

Secondary outcome

Secondary study outcomes are the number of patients with saturations to <=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

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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