

# Anaesthesia with dexmedetomidine and fentanyl for surgery in newborn babies

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| <b>Submission date</b><br>01/01/2017   | <b>Recruitment status</b><br>No longer recruiting | <input checked="" type="checkbox"/> Prospectively registered<br><input type="checkbox"/> Protocol            |
| <b>Registration date</b><br>10/01/2017 | <b>Overall study status</b><br>Completed          | <input type="checkbox"/> Statistical analysis plan<br><input type="checkbox"/> Results                       |
| <b>Last Edited</b><br>16/02/2018       | <b>Condition category</b><br>Surgery              | <input type="checkbox"/> Individual participant data<br><input type="checkbox"/> Record updated in last year |

## Plain English summary of protocol

### Background and study aims

Anaesthesia (sedation) and surgery in newborn babies (neonates) is only performed if absolutely necessary, as they have a high risk of developing complications related to their airways, breathing and heart function. In addition, a large number of recent animal studies have raised concerns that the newborn brain is vulnerable to damage caused by common drugs used for anaesthesia. Fortunately, to date there is no evidence that this damage occurring in humans, but studies to discover even subtle changes in the brain are hard to perform in humans. Alpha-2-agonists are a type of anaesthetic drug that are not associated with damage to the brain in animal studies. In fact, they even seem to have a protective effect against the damage associated with other drugs. One of the alpha-2-agonists is called dexmedetomidine. It is used as a sedative in intensive care, both for adults and children. It may also be used for anaesthesia, although there is very limited experience of this in new born babies. The aim of this study is to find out whether a potentially damaging drug called sevoflurane which is commonly used for anaesthesia, can be replaced by dexmedetomidine in anaesthesia induced (started) using a drug called fentanyl.

### Who can participate?

Newborn babies who are scheduled to undergo major surgery requiring anaesthesia with high dose fentanyl

### What does the study involve?

In the first part of the study, four patients receive routine anaesthesia with fentanyl (a potent drug for treatment of pain) and sevoflurane (an anaesthetic drug), with some extra monitoring of heart and brain function. In the second part of the study, another four patients receive anaesthesia with a low dose of dexmedetomidine, replacing sevoflurane. If there are no serious side effects, then a third group of four patients receives anaesthesia with a higher dose of dexmedetomidine, replacing sevoflurane. Participants in all groups are then monitored for side effects and pain levels for 24 hours after surgery.

### What are the possible benefits and risks of participating?

There are no direct benefits to those taking part, although their participation will help the research team learn more about the potentially protective effects of dexmedetomidine during

anaesthesia and its' pain relieving effects during the period after surgery. There is a risk of unexpected effects of heart rate and blood pressure, however patients are closely monitored and such effects, should they occur, may easily be treated by the anaesthetic team.

Where is the study run from?

Uppsala University Hospital (Sweden)

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

March 2016 to March 2018

Who is funding the study?

Uppsala County Council (Sweden)

Who is the main contact?

Dr Peter Frykholm

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## Contact information

**Type(s)**

Scientific

**Contact name**

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## Additional identifiers

**Clinical Trials Information System (CTIS)**

2016-004264-19

**Protocol serial number**

NEODEX2

## Study information

**Scientific Title**

Anaesthesia with dexmedetomidine and fentanyl for neonatal surgery: A pilot study

**Acronym**  
NEODEX2

**Study objectives**

The aim of this pilot study is to assess the feasibility of using dexmedetomidine as an alternative to sevoflurane together with high dose fentanyl for neonatal anesthesia.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Uppsala IRB, 05/04/2017, ref: Dnr 2017/012

**Study design**

Interventional non-randomised pilot study

**Primary study design**

Observational

**Study type(s)**

Treatment

**Health condition(s) or problem(s) studied**

Anaesthesia

**Interventions**

In the first stage of the study, a control group of four patients are subjected to standard anaesthesia monitoring + NIRS and CFM). The anaesthesia is routine anaesthesia based on fentanyl 10 microgram/kg and atracurium 0.5 mg/kg at induction, with repeat doses at the start of surgery and if indicated due to a long procedure, and sevoflurane up to 1%.

In the second stage, four patients receive anaesthesia with a low dose of dexmedetomidine initially replacing sevoflurane. At induction, dexmedetomidine 0.4 microgr/kg bolus, then 0.6 microgr/kg/h maintenance with a possibility to titrate to max 1 micrograms/kg/h. Sevoflurane is given only as a "rescue" medication, if the anaesthesia is judged to be inadequate.

After completion of the second stage, an interim analysis is performed. If there were no serious adverse events (hypotension or bradycardia needing intervention with adrenaline or hypoglycaemia needing repeated interventions with glucose administration), and at least two anaesthetics could be completed without sevoflurane, the study is continued with the third stage.

In the third stage, four patients receive the same protocol as in stage two but with a higher dexmedetomidine dose of: bolus 0.7 microgr/kg, maintenance 1 microgr/kg/h, with possible titration up to 2 microgr/kg/h.

Incidence of adverse events is monitored for 24 hours after surgery in all participants.

**Intervention Type**

Drug

**Phase**

Phase II

**Drug/device/biological/vaccine name(s)**

Dexmedetomidine

**Primary outcome(s)**

Rate of completion of anaesthesia without the addition of rescue anaesthetics (propofol or sevoflurane) and with hemodynamic stability is assessed at the end of the surgery when the patient is handed over to the ICU team.

**Key secondary outcome(s)**

1. Incidence of adverse events is assessed 24 hours after the end of surgery
2. Postoperative opioid consumption is assessed 24 hours after the end of surgery
3. Postoperative pain is assessed using N-PASS four-hourly until 24 hours after the end of surgery

**Completion date**

31/03/2018

**Eligibility****Key inclusion criteria**

1. Admitted to neonatal intensive care unit
2. Scheduled for major abdominal or thoracic surgery requiring anaesthesia with high dose fentanyl (30 micrograms/kg)
3. Delayed extubation is planned, permitting the use of high dose fentanyl
4. Gestational age 39-44 weeks
5. Aged up to one month old

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Neonate

**Sex**

All

**Key exclusion criteria**

1. Extubation planned in the operation theatre
2. Haemodynamic instability requiring inotropic support
3. Weight < 2 kg.
4. Gestational age < 37 weeks or > 44 weeks
5. Treatment with alpha-2-agonist within 12 hours before surgery

**Date of first enrolment**

01/03/2017

**Date of final enrolment**

28/02/2018

## Locations

**Countries of recruitment**

Sweden

**Study participating centre**

**Uppsala University Hospital**

Department of Anaesthesia and Intensive Care

Uppsala

Sweden

751 85

## Sponsor information

**Organisation**

Uppsala County Council

**ROR**

<https://ror.org/01dv86r63>

## Funder(s)

**Funder type**

Government

**Funder Name**

Uppsala County Council

## Results and Publications

**Individual participant data (IPD) sharing plan**

The current data sharing plans for the current study are unknown and will be made available at a later date.

**IPD sharing plan summary**

Data sharing statement to be made available at a later date

**Study outputs**

| Output type                                   | Details                       | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|-------------------------------|--------------|------------|----------------|-----------------|
| <a href="#">Participant information sheet</a> | Participant information sheet | 11/11/2025   | 11/11/2025 | No             | Yes             |