Efficacy of single dose intranasal dexmedetomidine for conscious sedation in dental practice in dentophobic uncooperative patients with intellectual disability

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Dexmedetomidine when used intranasally fopr procedural sedation does not significantly decrease the proportion of patients with intellectual disability and dentophobia needing general anesthesia for dental treatemnt

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON28972

Bron
NTR

Verkorte titel
KUKIDEX-2

Aandoening

Dentophobia
Intelelctual disability

Ondersteuning

Primaire sponsor: UMCG
Overige ondersteuning: UMCG

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

• Proportion of patients in whom dental treatment

under procedural sedation with intranasal dexmedetomidine

can be finished and is not terminated because of inadequate

sedation.

• Proportion of patients in whom dental treatment

under general anesthesia can be finished and is not

terminated because of inadequate sedation.

• mRASS-score at specified dental treatment events

after dexmedetomidine treatment compared to agitation

score descriptor from the non-pharmacological Trial-of-

Treatment

• mRASS-score at specified events during induction for

general anesthesia compared to agitation score descriptor

from the non-pharmacological Trial-of- Treatment

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: Many patients with intellectual disability lack adequate cognitive strategies to cope with the stress and fear accompanying medical or dental treatment. This makes surgical or dental procedures for these patients stressful if not impossible to tolerate without general anesthesia. Although general anesthesia provides the certainty of good access to the patient, the workup, induction and emergence of general anesthesia is often even more stressful for this vulnerable group of patients. A safe and reliable sedative with a quick and easy route of administration can provide patient comfort and ensure good cooperation and access.

Intranasal administration of dexmedetomidine has been proven to be quick, comfortable and reliable in providing dose dependent sedation levels ranging from premedicative anxiolysis to deep conscious sedation. The literature only bases these conclusions on studies in adults with full cognitive function or children. Theoretically dexmedetomidine may provide an excellent alternative to more commonly used sedatives like benzodiazepines. Dexmedetomidine's sympathicolytic effect can alleviate fear not by suppressing the cerebral projection of fear but by reducing the intrinsic activity of the brainstem arousal system and of the autonomous nervous system. Especially for patients without the cognitive coping abilities this may provide good and safe sedation. The study will focus on the feasibility and efficacy of dexmedetomidine for conscious sedation after nasal administration in these patients.

Objective: To demonstrate non-inferiority of conscious

sedation with intranasal dexmedetomidine for performing

dental care in patients with intellectual disability and

dentophobia.

Study design: A single centre therapeutic randomized

non-inferiority study.

Study population: 30 ASA 1-3 patients with intellectual disability (mild to profound) who require dental examination or treatment, but in whom dental examination or treatment was not possible without pharmacological support in the dental policlinic 'Bijzondere Tandheelkunde' because of severe dentophobia.

Intervention: Intranasal administration of 1,5 mcg/kg dexmedetomidine (using a medical atomizer device).

Main study parameters/endpoints:

• Proportion of patients in whom dental treatment

under procedural sedation with intranasal dexmedetomidine

can be finished and is not terminated because of inadequate

sedation.

• Proportion of patients in whom dental treatment under general anesthesia can be finished and is not terminated because of inadequate sedation.
• mRASS-score at specified dental treatment events after dexmedetomidine treatment compared to agitation score descriptor from the non-pharmacological Trial-of-Treatment
• mRASS-score at specified events during induction for general anesthesia compared to agitation score descriptor from the non-pharmacological Trial-of- Treatment

This is a therapeutic trial. Participation in the study can provide several benefits to the patients.
Induction of general anesthesia is a frightening event for PwID whose ability to deal with fear on a cognitive basis is reduced. Being hooked up to the monitoring system, the need to breath in a ventilator mask with the strange smell of volatile anesthetics or the placing of an intravenous canula are all fearfull moments. This often leads to necessary but very unwanted cases of frightened, fighting patients. Not seldom do these patients have to be restrained for their own good.
It is the inability to cope with stress and fear on a cognitive basis that forms the group relatedness for this specific trial. Dealing with frightened PwIDs is completely different from dealing with frightened patients with full cognitive

capabilities. There is no conceiveable substitute for the unique clinical problem faced by the specialized dentist and the anesthetist.

Patients will receive either the standard care (dental treatment under general anesthesia) or they will reiceve anxiolytic procedural sedation. In either case the planned, necessary dental treatment will be completed. Patients who can not be treated with dexmedetomidine procedural sedation alone will receive a general anesthetic in the same procedure to complete their dental treatment. Even if the full dental treatment cannot be completed after dexmedetomidine administration, the sedative effects of IN dexmedetomidine will make tolerance of usually unpleasant procedures easier and less frightening. Studies in children and adults without intellectual disabilities have shown that dexmedetomidine is well tolerated when administered intranasally by either droplets or atomizer spray. In children and adults without intellectual disabilities, the dose used has been shown to be safe and effective.

The presence of a dedicated anaesthesiologist will be constant during the study period in which dexmedetomidine is used. The sedation with dexmedetomidine has no implications for general anesthesia (should this be indicated) that can not easily be accommodated for by the attending anesthetic team.

Tolerance of the treatment is measured constantly by

sedation and agitation scores. When a patient has a

sedation/agitation score indicating less tolerance to

treatment under sedation compared to treatment in the OPD,

this signals that the treatment is no longer in the patients

best interest and they will receive standard institution

treatment (i.e. be converted to GA) and study procedures

will stop.

The dentist in attendance is a specialist in providing dental

care to specifically this vulnerable group of patients, and is

trained in using both non-pharmacolgical and

pharmacological strategies in the treatment of PwIDs and

dentophobia.

No follow up visits will be required.

After the dental procedure the subject will be in normal post-surgical care. The study medication is not expected to have implications for this period. As is normal after procedural sedation and daycare surgery under general anesthesia, subjects will be discharged with adult supervision and will be asked to spend the night following the procedure under the care of a responsible adult. Subjects not planned for daycare surgery will be admitted to the ward as is normal. No follow up visits will be required.

Doel van het onderzoek

Dexmedetomidine when used intranasally fopr procedural sedation does not significantly decrease the proportion of patients with intellectual disability and dentophobia needing general anesthesia for dental treatemnt

Onderzoeksopzet

Start of dental treatment until completion of dental treatment or until induction of general anesthesia

Onderzoeksproduct en/of interventie

Single dose intranasal administration of dexmedetomidine

Contactpersonen

Publiek

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Intellectual Disability of DSM-V classes Mild to

Profound

2. Failure to tolerate the indicated dental treatment

with non-pharmacological support.

3. Indication for dental treatment under general

anesthesia because of 1 and 2.

4. Completed and cleared through the pre-anesthetic

screening as per the standard protocol of the UMCGs

department of anesthesiology

5. Adult, men and women, 18-65 years of age,

inclusive.

6. Body Mass Index (BMI) ≥ 17.5 and ≤ 35 kg/m2,

inclusive, and a total body weight >50 kg, at screening and

check-in.

7. American Society of Anesthesiologists (ASA) Physical

Status 1-3

8. Able to understand the study procedures as

described in the patient information sheet, willing and able to

comply with the protocol, and to provide written informed

consent OR in the case of legal incapability: a guardian

understanding the study procedures as described in the

patient information sheet, provides written informed consent.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Contraindications for the use of dexmedetomidine

2. Known intolerance to dexmedetomidine

3. History or presence of significant cardiovascular

disease (ASA >3), or significant cardiovascular disease risk

factors, significant coronary artery disease, or any known

genetic pre disposition to cardiac arrhythmia (including long

QT syndrome.)

4. History or presence of significant (ASA >3)

pulmonary, hepatic, renal, hematological, gastrointestinal, endocrine, immunologic, dermatologic, neurological, disease.

5. History of any illness or medication use that, in the opinion of the PI, might confound the results of the study or pose an additional risk to the subject by their participation in the study.

6. Difficulty in airway management anticipated by the attending anesthesiologist .

7.

8. Surgery within the past 90 days prior to dosing judged by the PI to be clinically relevant.

9. History of febrile illness within 5 days prior to dosing.

10. History or presence of alcoholism or drug abuse within the past 2 years.

11. Hypersensitivity or idiosyncratic reaction to components of dexmedetomidine, , or to compounds related to the study medications.

12. Patients refusal or, in case of legal incapability:

13. Guardians refusal

Onderzoeksopzet

Opzet

Type: Interventie onderzoek

Onderzoeksmodel:	Anders
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-09-2016
Aantal proefpersonen:	30
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL5663
NTR-old	NTR5798

Register	ID
Ander register	UMCG Research Register : 201600438

Resultaten