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

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To demonstrate non-inferiority of conscious sedation with intranasal dexmedetomidine for performing dental care in patients with intellectual disability and dentophobia.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON43058

Source
ToetsingOnline

Brief title
KUKIDEX-2

Condition

- Other condition
- Anxiety disorders and symptoms

Synonym
dentophobia, fear for dentist

Health condition

Verstandelijke beperking

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: conscious sedation, dentophobia, intellectual disability

Outcome measures

Primary outcome

* 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

Secondary outcome

* Tolerance (mRASS) of achieving venous access when general anesthesia is indicated

* Ease of induction when general anesthesia is indicated as measured by RASS

during induction

Study description

Background summary

Many patients with intellectual disability (PwIDs) 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. Safe and reliable sedation with a quick and easy route of administration can provide patient comfort and ensure good cooperation and access. It would also mean these patients can be treated in office- or home based settings, negating the need for several hospital visits.

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.

Study 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 center randomized therapeutic non-inferiority study

Intervention

Patients for whom consent has been obtained will already have completed a treatment in the Specialized dentistry department to complete dental treatment without pharmacological support. The indication for treatment under general

anesthesia comes from the failure to complete this treatment. These patients have an indication for treatment under general anesthesia. Participants are randomized 1:1 to receive either standard treatment (general anesthesia) or treatment under procedural sedation (dexmedetomidine)

After randomization for treatment under general anesthesia,the normal procedure is followed for induction of general anesthesia. After randomization for treatment with dexmedetomidine a single dose dexmedetomidine is given intranasally by atomizer device. After a latency period of 20-30 the planned dental treatment will start.

For both treatment groups, a modified mRASS score is noted during the treatment. The stages of this score have been rafted by dentists of the Special dentistry department of the UMCG en have been matched to stages of induction of general anesthesia with similar levels of confrontation. For the general anesthesia group the mRASS is noted during induction of general anesthesia. For the dexmedetomidine group the mRASS is noted during dental treatment.

The mRASS score is a specialized modificiton of the well recognized RASS score. The scores descriptors have been modified to describe clinical signs of agitation and sedation fitting the events of dental treatment. When mRASS scores supersede the pre-treatment mRASS scores form the policlinic phase continuation of treatment under dexmedetomidine sedation is longer deemed to be in the best interest of the patient and a conversion to general anesthesia is initiated after which planned dental treatment can be finished.

In accordance with the Code of Conduct "Verzet bij mensen met een verstandelijke handicap in het kader van de Wet Medisch-Wetenschappelijk Onderzoek met Mensen" guardian of the patient will be present to observe the tolerance of treatment and to inform the dentist and the researcher when the reaction of the patient is notably different or more excessive from reactions typical to the patient when encoutering other abnormal situation.

Study burden and risks

Participation in the study can provide several benefits to the patients. When treatment under sedation is well tolerable, they will be spared the stressfull events of an induction of general anesthesia. When the treatment is not tolerable, the anxiolytic properties of dexmedetomidine have a calming effect which will make the events of the induction of general anesthesia more beareable.

This is a therapeutic trial. Participation can have several benefits to patients. Participants in the therapeutic arm (sedation) will receive their planned treatment even when the treatment under sedation is not tolerable to them.

When mRASS scores supersede the pre-treatment mRASS scores form the policlinic phase continuation of treatment under dexmedetomidine sedation is longer deemed to be in the best interest of the patient and a conversion to general anesthesia is initiated after which planned dental treatment can be finished.

All clinicians and researchers involvoed will act in accordance with the Code of Conduct "Verzet bij mensen met een verstandelijke handicap in het kader van de Wet Medisch-Wetenschappelijk Onderzoek met Mensen." A guardian of the patient will be present to observe the tolerance of treatment and to inform the dentist and the researcher when the reaction of the patient is notably different or more excessive from reactions typical to the patient when encoutering other abnormal situations.

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.

No follow up visits are required.

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

1. Intellectual Disability of DSM-V classes Mild to Profound
2. Documented 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 for general anesthesia as per the standard protocol of the UMCGs department of anesthesiology
5. Adult, men and women, 18-55 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.

Exclusion criteria

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 difficult airway management excpected by the attendind anesthesiologist
7. Surgery within the past 90 days prior to dosing judged by the PI to be clinically relevant.
8. History of febrile illness within 5 days prior to dosing.
9. History or presence of alcoholism or drug abuse within the past 2 years.
10. Hypersensitivity or idiosyncratic reaction to components of dexmedetomidine, , or to compounds related to the study medications.
11. Patients refusal or, in case of legal incapability:
12. Guardians refusal

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	24-11-2016
Enrollment:	30
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Dexdor
Generic name:	Dexmedetomidine
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	20-07-2016
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	24-11-2016
Application type:	First submission

Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	01-11-2017
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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
EudraCT	EUCTR2016-001567-37-NL
CCMO	NL57519.042.16