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Fasting versus non-fasting intravenous sedation in the dental setting

Submission date
14/07/2017

Recruitment status
No longer recruiting

Registration date
11/08/2017

Overall study status
Completed

Last Edited
11/08/2017

Condition category
Oral Health

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Dental anxiety is when patients feel nervous, worried or uneasy about going to the dentist. Almost one out of two patients suffer from moderate to severe dental anxiety. A very efficient, cost effective and low risk method to manage dental anxiety is conscious sedation. Conscious sedation is a combination of medicines to help patients relax (a sedative) and to block pain (an anesthetic) during a dental procedure. It is not known whether it is better to fast or not before sedation. This is due to lack of high quality evidence to effectively support one or the other. Further research will help to improve knowledge of the subject and provide better healthcare and treatment to patients by reducing the side effects of sedation. The aim of this study is to compare sedation-related complications, the dose of the sedation drug, and the recovery time needed after sedation in fasting and non-fasting patients.

Who can participate?
Patients aged 17-65 undergoing oral surgery under sedation

What does the study involve?
Participants are randomly allocated to either the fasting group or the non-fasting group. Sedation-related complications, the dose of the sedation drug, and the recovery time needed after sedation are compared between the two groups.

What are the possible benefits and risks of participating?
No additional benefits or risks are expected for the participants, but the results may help to develop guidelines that will benefit patients in the future.

Where is the study run from?
Edinburgh Dental Institute (EDI) and Chalmers Dental Centre (CDC) (UK)

When is the study starting and how long is it expected to run for?
September 2017 to March 2020

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr Vasileios Lyris

Contact information

Type(s)
Scientific

Contact name
Dr Vasileios Lyris

Contact details
24/6 Clerk Street
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
224757

Study information

Scientific Title
Fasting versus non-fasting prior to intravenous sedation in the dental setting: a single-blinded randomised trial

Study objectives
Patients who are not fasting have fewer complications than those fasting.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration - submission pending

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Intravenous sedation in the dental setting

Interventions
The patient information sheet for this project is sent with the letter for the new patient appointment. Then when the patients are seen in the Edinburgh Dental Institute or the Chalmers Dental Centre for their new patients appointment, all potential participants planning to undergo IV sedation are given the patient information sheet (again) as well as the consent form and they are asked them if they are willing to participate. If the patient agrees to participate, he/she will sign the consent form and will be given an envelope with the "Fasting" or "Non-Fasting" instructions. Patients are randomised according to a randomisation sequence generated by www.randomizer.org.
1. The "Non-Fasting envelope" will advise the patients to eat normally on the day of their appointment, avoiding alcoholic drinks and large meals
2. The "Fasting envelope" will follow the 6-4-2 protocol which is: six hours prior to sedation for solid food, four hours for non-clear drinks (e.g. milk, orange juice, etc), and two hours for clear fluids like water

The patient will be advised to review more carefully the patient information sheet at home and 2-3 weeks prior to his/her sedation appointment will be contacted to re-confirm willingness to participate and get reminded of what to do according to the envelope that he/she has got. The surgical procedure may be performed by member or members of the research team, or any other clinician of the oral surgery team of the Edinburgh Dental Institute and Chalmers Dental Centre. The patients will be asked by the responsible clinician if they have fasted or not for safety reasons and in order to get the best possible care. After the surgical appointment, the clinical notes are going to be transferred in the Case Report Form, and the form is going to be locked away. All the data required to be completed in the Case Report Form is the pre-operative, intra-operative and post-operative data that is normally collected in the Edinburgh Dental Institute and Chalmers Dental Centre. The sedation drug used is the one used in the standard protocol, midazolam. For some patients, if deemed necessary the reversing agent might be needed to be used, flumazenil.

The duration of treatment is relative and it depends upon the waiting times for intravenous sedation appointments at the Edinburgh Dental Institute and Chalmers Dental Centre. These range from 2-3 months from the time of the new patient clinic appointment until the time of treatment.

The data will be analysed using Microsoft Excel (Microsoft Corporation, Redmond, WA, USA). Descriptive statistics will be used to present mean values with standard deviations and 95% confidence intervals where appropriate. Independent t-tests will be used for continuous numerical and differences will be tested for statistical significance using the chi-squared x^2 test. Statistical significance will be defined as $p<0.05$. Patients that will drop out or patients with missing data will be excluded from the analyses but they will be mentioned in the discussion part of the study.

Intervention Type
Other

Primary outcome measure
The incidence of pre-operative (cannulation), intra-operative and post-operative (recovery) complications following intravenous sedation procedures, recorded using the Case Report Form on the day of the operation and until the time of discharge of the patient upon recovery

Secondary outcome measures
1. Dose of drug used (midazolam), recorded using the Case Report Form on the day of the operation
2. Recovery time, recorded using the Case Report Form at the time of discharge of the patient upon recovery

Overall study start date
18/09/2017

Completion date
06/03/2020

Eligibility

Key inclusion criteria
1. NHS patients at Edinburgh Dental Institute (EDI) and Chalmers Dental Centre (CDC) planned to undergo oral surgery procedure under intravenous sedation
2. Aged 17-65
3. Classified as ASA I or ASA II
4. Male and female patients
5. Able to give consent

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
732 in two groups of 366 each

Key exclusion criteria
1. Patients having general anaesthesia
2. Patients having procedures under local anaesthetic alone
3. Patient not able to give consent
4. ASA 3 and ASA 4
5. Patient not willing to participate
6. Patient unable to undertake sedation under midazolam
7. Patients unable to fast e.g. patients with type 1 diabetes mellitus or eating disorders
8. Patients taking St John's Wort

Date of first enrolment
18/09/2017

Date of final enrolment
06/02/2020

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre
Edinburgh Dental Institute
Edinburgh
United Kingdom
EH3 9HA

Study participating centre
Chalmers Dental Centre
Edinburgh
United Kingdom
EH3 9EW

Sponsor information

Organisation
The Queen's Medical Research Institute

Sponsor details
c/o Mr Chris Conner
47 Little France Crescent

Edinburgh
Scotland
United Kingdom
EH16 4TJ

Sponsor type
Hospital/treatment centre

Website
http://accord.scot/

ROR
https://ror.org/01nrxwf90

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal within 12 months of the completion of the trial.

Intention to publish date
06/03/2021

Individual participant data (IPD) sharing plan
The 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