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Comparison between a needle-free system (Comfort-In) and needle dental anaesthesia in adult volunteers

Submission date	Recruitment status	[_] Prospectively registered
22/11/2020	No longer recruiting	[_] Protocol
Registration date	Overall study status	[_] Statistical analysis plan
18/01/2021	Completed	[X] Results
Last Edited	Condition category	[_] Individual participant data
30/04/2021	Oral Health	

Plain English summary of protocol

Background and study aims
Anaesthesia is administered prior to a procedure to help dull pain or sedate a nervous or anxious patient. The most common form is local anaesthesia, meaning that it dulls pain in all or part of the mouth during dental work, but does not cause the patient to go to sleep.
The aim of the study is to compare dental anaesthesia injected with a needle to a needle-free device (Comfort-In) in adults.

Who can participate?
Healthy adult volunteers, aged 19-40 years, who had received dental anaesthesia in the past without dental phobia or other phobias.

What does the study involve?
One technique is applied on the right side and the other on the left side sequentially on the same day by the same dentist. Then several tests will be performed every few minutes in order to check which technique is more effective. During the procedure, participants will be asked several questions to make sure that the techniques are well tolerated. At the end of the session, at 24 hours and 7 days, all participants are asked to report any side-effects or complications and which of the two techniques they prefer.

What are the possible benefits and risks of participating?
There are no direct benefits for participants, but their contribution to research is valuable. There are no risks apart from those associated with dental anaesthesia.

Where is the study run from?
Dental School of the Aristotle University of Thessaloniki (Greece)

When is the study starting and how long is it excepted to run for?
September 2018 to July 2019

Who is funding the study?
The study received no funding. Comfort-In device and all the consumables were granted by Nordiga Medical Devices (http://www.nordiga.gr).

Who is the main contact?
Apostolina Theocharidou, koarap@dent.auth.gr

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
29/21.11.2018

Study information

Scientific Title
Comparison of efficacy, acceptance and preference between Comfort-In local anaesthetic device and conventional infiltration technique in adult volunteers

Acronym
JetorConv

Study objectives
Jet injection via Comfort-in device is superior to conventional local infiltration anaesthesia in terms of efficacy, acceptance and preference amongst adult volunteers.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Approved 28/11/2018, Ethics Committee of Dental School (Aristotle University of Thessaloniki School of Health Sciences School of Dentistry, Central Secretariat, A Lower ground, 54124, Thessaloniki, Greece; +302310999471; info@dent.auth.gr), ref: 29/21.11.2018

Primary study design
Interventional

Study design
Interventional single-centre randomized controlled split-mouth study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Method of dental anaesthesia

Interventions
Upper premolars without any restorations or caries and with vital pulp tissue were chosen to be anaesthetized. One technique was applied on the right side whilst the other on the left side sequentially on the same day by the same operator. The anaesthetic solution comprised of 0.3ml of articaine 4% (1/200000 epinephrine) for both techniques. The quadrant and the order of administration were randomly assigned using an online randomization generator. Immediately after administration, at 3, 5, 10, 15, 20, 25 and 30 minutes, pulp vitality and soft tissue pain reaction tests were performed. At the end of the session, at 24 hours and 7 days, all participants were asked to report any adverse events and their preference. Blinding was not possible neither for the participants nor for the operator.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Comfort-in device

Primary outcome(s)
Measured at 3, 5, 10, 15, 20, 25 and 30 minutes (unless otherwise noted):
1. Pulp vitality measured using electric pulp test (Pulppen DP2000 Digital, Dental Electronic)
2. Pulp sensitivity measured using the cold test (ethyl chloride spray)
3. Soft tissue pain measured using the reaction test (pinch via a pair of forceps)
4. Acceptance during the session and preference at the end of the session, at 24 hours and at 7 days were measured via questionnaires

Key secondary outcome(s)
1. Length of subjective feeling of numbness was self-reported by volunteers at 24 hours
2. Adverse events were self-reported by volunteers at 24 hours and at 7 days

Completion date
07/07/2019

Eligibility

Key inclusion criteria
1. Healthy adults, aged 19 - 40 years
2. History of previous dental anaesthesia
3. Present upper premolars with vital pulp tissue

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
63

Key exclusion criteria
1. History of dental phobia or any other phobia
2. History of drug or substance abuse
3. Upper premolars with restorations/caries
4. Pregnant women

Date of first enrolment
30/03/2019

Date of final enrolment
30/06/2019

Locations

Countries of recruitment
Greece

Study participating centre
Aristotle University of Thessaloniki
School of Health Sciences
School of Dentistry
Thessaloniki
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54124

Sponsor information

Organisation
Aristotle University of Thessaloniki

ROR
https://ror.org/02j61yw88

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Funder Name
Nordiga Medical Devices

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request. Data will be provided in an excel file. They will be available for 10 years since the completion of the study. They will be shared with other researchers for systematics reviews and meta-analyses. Consent from participants was obtained. There is anonymisation of the data.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/04/2021	30/04/2021	Yes	No