ISRCTN10930940 https://doi.org/10.1186/ISRCTN10930940

Can a mechanically controlled compression of the upper lip reduce the perception of pain during a local anesthetic injection in the mouth?

Submission date 29/12/2019	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol
Registration date 02/01/2020	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 10/01/2020	**Condition category** Oral Health	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol

Background and study aims
One of the most uncomfortable aspects of the dental appointment is the pain associated with the dental injection, which can cause anxiety and fear. Previous studies using this theoretical basis have shown that the vibration on the skin of the lip or different parts of the face can reduce the intensity of the pain coming from teeth or soft tissues. However, there have been no reports that quantify the effectiveness of using tissue compression near the puncture site in order to verify its efficacy in reducing pain perception during local dental anesthesia administration. Therefore, the aim of this study was to assess the effect of controlled compression of the upper lip on reducing the perception of pain during a local maxillary anesthetic injection.

Who can participate?
Dental students aged 18 years or older from Austral University of Chile Dental School

What does the study involve?
Participants will receive anesthetic using compression of the upper lip with wooden clothes peg and anesthetic without compression in a random order.

What are the possible benefits and risks of participating?
Benefits: The benefit is that the patient will perceive less pain at the time of the administration of the local anesthetic and will provide greater comfort for the dental treatment in the anesthetized area.
Risks: There are no major risks, only the risks inherent in any anaesthetic technique.

Where is the study run from?
Dental School, Faculty of Medicine, School of Dentistry, Austral University of Chile

When is the study starting and how long is it expected to run for?
June 2018 to November 2018

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr Pedro Aravena
paravenat@gmail.com

Contact information

Type(s)
Public

Contact name
Dr Pedro Aravena

ORCID ID
https://orcid.org/0000-0003-1230-4573

Contact details
Rudloff Street #1640
Valdivia
Chile
5110434
+56 632221205
paravena@uach.cl

Additional identifiers

Protocol serial number
13/01/2016

Study information

Scientific Title
Effect of upper lip compression on pain control during local maxillary anesthesia. A Split-mouth randomized clinical trial

Study objectives
Upper lip compression reduces pain perception during a local maxillary anesthetic injection

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 13/01/2016, Ethical Committee of Faculty of Medicine. Universidad Austral de Chile (Austral University of Chile, Medicine Faculty, Campus Isla Teja S/N, Valdivia, 5110434 - Chile; +56 63 2221324; facmed@uach.cl), ref: n/a

Primary study design

Interventional

Study design
Split-mouth randomized clinical trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Local maxillary anesthetic injection

Interventions
To determine the chronological order of the injection for to control the measurement bias and placebo effect of lip compression, a randomization process within subject was performed using software available at http://www.sealedenvelope.com by a staff member not involved in the research protocol, who recorded the details of the allocated group on cards contained in sequentially opaque, numbered and sealed envelopes. The allocation assignment was revealed by opening the envelope immediately before of the procedure, where cards containing one of two colors were used, indicating the primary intervention: red meant anesthetic using compression with wooden clothes peg and white card meant anesthetic without compression. Thus, the concealment of the random sequence was guaranteed, in order to prevent selection bias.
In order to control for the effect different time may have an influence on the pain perception, all measurement was applied between 10:00 to 12:00 hours of the day. In preparation for the anesthetic, the volunteers rinsed with a mouthwash of 0.12% chlorhexidine (OralgeneTM, MaverPharma. Chile) and were positioned in the dental chair as described by Malamed for local maxillary anesthetic techniques. One investigator (JL) prepared the carpule syringe using a 30G short needle (Septoject XL, SeptodontTM. Saint-Maur-des-Fossés, Francie) and a Xylonor 2% special anesthesia cartridge (SeptodontTM) at room temperature. For the volunteer selected for anesthesia with lip compression, the investigator responsible for the anesthetic technique, trained and with 10 years of experience in the dental emergency service (PCA), placed the wooden clothes peg on the upper lip at the level of the left upper canine, separating the lip with the use of a dental mirror, next to the puncture site and immediately performed the anesthetic technique according to the recommendations made by Malamed, placing the needle parallel to the lateral incisor and going down to one centimeter from the bottom of the buccal plate, depositing a third (0.6 ml) of the contents of the anesthesia cartridge within 15 seconds. Immediately after withdrawing the needle, the second investigator (JL) presented the volunteer with a card with the VAS, asking “How much pain did you perceive during the puncture and administration of the anesthesia?” and registering the value indicated. The principal investigator did not participate in the collecting or recording of the data. After two weeks (the washout period), the second injection was done on the contralateral side of the maxilla with the same technique and the complementary intervention according to the randomization sequence described.

Intervention Type
Drug

Phase
Phase IV

Drug/device/biological/vaccine name(s)

Xilonor 2% (2% Lidocaine with 1:100.000 Epinephrine)

Primary outcome(s)
The level of pain perceived by the volunteer on the Visual Analogue Scale (VAS) during the anesthetic injection recorded at the time of injection

Key secondary outcome(s)
Covariance of the main outcome (pain perception during anaesthetic injection) according to variables such as sex and age of participants.

Completion date
30/11/2016

Eligibility

Key inclusion criteria
1. Aged 18 years or older
2. Signed informed consent form

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Total final enrolment
72

Key exclusion criteria
1. History of allergies or adverse reactions to local anesthesia
2. Presence of dental pain because of dental or orthodontic treatment one month prior to the study
3. Infection in the puncture area
4. Pharmacological treatment with non-steroidal anti-inflammatory drugs (NSAIDs), benzodiazepines or antidepressants

Date of first enrolment
01/04/2016

Date of final enrolment
30/06/2016

Locations

Countries of recruitment
Chile

Study participating centre
Dental School, Faculty of Medicine, School of Dentistry
Austral University of Chile
Valdivia
Chile
5110434

Sponsor information

Organisation
Austral University of Chile

ROR
https://ror.org/029ycp228

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
All data generated or analysed during this study will be included in the subsequent results publication.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?

Protocol file	10/01/2020	No	No