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Effect of temperature local dental anesthetics on injection pain

Submission date	Recruitment status	[_] Prospectively registered
12/03/2015	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
04/08/2015	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
01/09/2020	Oral Health	

Plain English summary of protocol

Background and study aims
The use of local anesthesia in dental service causes immediate pain and discomfort during injection, causing many people to fear dental care. Previous reports, however, have suggested that heating the content of the anesthetic tube at a temperature between 37°C and 42°C results in significantly less pain. The aim of our research is to determine whether local anesthesia heated at 42°C causes less pain when administered compared to room temperature (21°C).

Who can participate?
Volunteer dental students for School of Dentistry of Austral University of Chile.

What does the study involve?
Each participant receives two local anesthesic injections. One side of the mouth is chosen at random to receive anesthesia warmed to 42 ° C. The other side receives anesthesia at room temperature (21°C). The two injections are administered by the same operator. Patients are then asked to describe their pain with reference to the Visual Analogue Scale VAS (0 = no pain, 10 = unbearable pain) immediately after each injection. Statistics are then used to analyse whether there is a significant difference in the amount of pain experienced.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
Dental Emergency Service"Dr Jorge Sabat Gozalo"of Valdivia city (Chile)

When is the study starting and how long is it expected to run for?
April 2015 to June 2015

Who is funding the study?
Austral University of Chile

Who is the main contact?
Dr Pedro Aravena

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Study information

Scientific Title
Effect of temperature local dental anesthetics on injection pain: a split mouth study

Study objectives
There is no differences between the level of perception of pain (Visual Analogue Scale - VAS) by increasing the temperature to 42 °C in local anesthetic compared to its implementation at 21°C in patients of Dental Emergency Service of Valdivia city - Chile between April-June 2015.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethical and Research Committee of Health Community Service of Valdivia, Chile, 16/03/2015, ref: 074/2915

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Perception of pain felt during dental procedures after administration of anesthesia

Interventions

In dental student volunteers, a dentist of Dental Emergency Service will administer in two points of the maxilla: One side with a 0,9 ml anesthesia (2% lidocaine with epinephrine 1: 100,000) in 42°C; and opposite side 0,9 ml of the same anesthetic in room temperature (21°C). Then, a researcher will show a Visual Analogue Scale with ten points (0=none pain to 10= unbearable pain) where the patient must indicate the intensity of perceived pain in the two points previously injected. The dentist and participants will be blind about the side of the injected site and the temperature of the cartridge anesthesia.

Intervention Type
Procedure/Surgery

Primary outcome(s)
1. Independent Variable: 2 groups of cartridge anesthesia temperature: cartridge in 42°C and cartridge in temperature room (21°C)
2. Dependent Variable: Intensity pain level (VIsual Analogue Scale - VAS) from 0 point (no pain) to 10 points (unbearable pain)

Key secondary outcome(s)
N/A

Completion date
30/06/2015

Eligibility

Key inclusion criteria
1. Students over the age of 18
2. Given their informed consent

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. Students with hypertension
2. Students with acute abscess or swelling at the injection site

Date of first enrolment
01/06/2015

Date of final enrolment
30/07/2015

Locations

Countries of recruitment
Chile

Study participating centre
Dental Emergency Service "Dr Jorge Sabat Gozalo" of Valdivia city - Chile
2500, Picarte Street.
Valdivia
Chile
5111434

Sponsor information

Organisation
Austral University of Chile (Universidad Austral de Chile)

ROR
https://ror.org/029ycp228

Funder(s)

Funder type
University/education

Funder Name
Austral University of Chile (Universidad Austral de Chile)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	22/02/2018	01/09/2020	Yes	No