

Effect of temperature local dental anesthetics on injection pain

Submission date 12/03/2015	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 04/08/2015	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 01/09/2020	Condition category Oral Health	<input type="checkbox"/> Individual participant data

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 anesthetic 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

Dr Pedro Aravena

ORCID ID

<http://orcid.org/0000-0003-1230-4573>

Contact details

Austral University of Chile (Universidad Austral de Chile)

Valdivia

Chile

5111434

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

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

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised cross over trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

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 measure

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)

Secondary outcome measures

N/A

Overall study start date

01/04/2015

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

42

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)

Sponsor details

Campus Isla Teja S/N.
Valdivia
Chile
5111434

Sponsor type

University/education

ROR

<https://ror.org/029ycp228>

Funder(s)

Funder type

University/education

Funder Name

Austral University of Chile (Universidad Austral de Chile)

Results and Publications

Publication and dissemination plan

Intention to publish date

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