# Effect of temperature local dental anesthetics on injection pain

| Submission date               | Recruitment status No longer recruiting | <ul><li>Prospectively registered</li></ul> |  |  |
|-------------------------------|---|--|--|--|
| 12/03/2015                    |   | ☐ Protocol                                 |  |  |
| Registration date             | Overall study status Completed          | Statistical analysis plan                  |  |  |
| 04/08/2015                    |   | [X] Results                                |  |  |
| <b>Last Edited</b> 01/09/2020 | Condition category Oral Health          | [] Individual participant data             |  |  |
| 01/03/2020                    | Oracineattii                            |  |  |  |

#### 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

Dr Pedro Aravena

#### **ORCID ID**

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

#### Contact details

Austral University of Chile (Universidad Austral de Chile) Valdivia Chile 5111434

## Additional identifiers

#### Protocol serial number

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

### 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              |