

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 2026

The effect of hypnosis in pain reduction during dental anesthetic infiltration

Protocol summary

Study aim

To determine the effect of hypnosis on pain relief due to injection of dental infiltration anesthesia

Design

Two arm parallel group randomized clinical trial with double blinding (dentist & the person who record the data) and participation of 32 patients

Settings and conduct

The study will be conducted at Dentistry School affiliated to Kurdistan University of Medical Sciences. The study will be double blind (Dentist & the person who record the data).

Participants/Inclusion and exclusion criteria

Inclusion criteria: being at the age of 15 and 25 years old; in need of double-sided restoration process of the first premolar teeth in the maxilla; ASA I, II. Non inclusion criteria: patients with heart problems, untreated epilepsy, patients with severe psychiatric disorders; low intelligence quotient (IQ)

Intervention groups

First intervention group: In the first session, first hypnosis is received and then the injection is performed, and in the second session on the other side of the jaw, the injection is received without hypnosis. Second intervention group: In the first session, injection is performed on one side of the jaw without hypnosis, and in the second session, first hypnosis and then injection on the other side of the jaw are performed.

Main outcome variables

Pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140504017562N3**

Registration date: **2020-06-22, 1399/04/02**

Registration timing: **retrospective**

Last update: **2020-06-22, 1399/04/02**

Update count: **0**

Registration date

2020-06-22, 1399/04/02

Registrant information

Name

Soma Arabzadeh Moghadam

Name of organization / entity

Kurdistan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 71 3654 1094

Email address

arabzade_s@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-11-29, 1398/09/08

Expected recruitment end date

2020-06-01, 1399/03/12

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of hypnosis in pain reduction during dental anesthetic infiltration

Public title

The effect of hypnosis in pain reduction during dental injection

Purpose

Diagnostic

Inclusion/Exclusion criteria

Inclusion criteria:
Volunteers who needed to receive restorative dentistry in the maxillary right and left first premolar teeth; ASA class I & II

Exclusion criteria:
Volunteers with heart problems Untreated epilepsy
Severe psychiatric disorders Low IQ

Age
From **15 years** old to **25 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **32**
More than 1 sample in each individual
Number of samples in each individual: **2**
Each person participating in the study is placed in a control group in one session and in another session in the intervention group

Randomization (investigator's opinion)
Randomized

Randomization description
Sampling method: patients are randomly allocated to either the intervention group A or control group B, it means that the first patient accidentally falls into one of the groups and the next patient falls into another group. This will continue until the study is completed.

Blinding (investigator's opinion)
Single blinded

Blinding description
Blinding method: The dentist who injects the anesthesia and the person who records the data are not present at the operating room while hypnosis is performed and they do not know which volunteer receives hypnosis.

Placebo
Not used

Assignment
Crossover

Other design features
Each participant in the study is placed in a control group in one session and in the next session in the intervention group, or vice versa. the intervention session and side of the maxilla is chosen randomly

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kurdistan University of Medical

Sciences
Street address
Pasdaran boulevard
City
Sanandaj
Province
Kurdistan
Postal code
66179-13446
Approval date
2018-07-17, 1397/04/26
Ethics committee reference number
IR.MUK.REC.1397.018

Health conditions studied

1

Description of health condition studied

The effect of hypnosis in pain reduction

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Pain score based on Visual Analogue Scale

Timepoint

Immediately after the intervention

Method of measurement

Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In intervention group, injection is performed with the same method and materials and equipment of the control group, along with hypnosis. A hypnosis's session is used to reduce the pain of the patients being studied and indirect induction techniques, dissociated techniques, telescopes and distraction are used. Also the duration of hypnosis varies from one person to another persons, because the hypnotic nature of the person varies from a few minutes to an hour.

Category

Diagnosis

2

Description

Control group: Injection without hypnosis

Category

Diagnosis

Recruitment centers

1

Recruitment center

Name of recruitment center

Dental School of Kurdistan University of Medical Sciences

Full name of responsible person

Soma Arabzade Moghadam

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Email

s.arabzade@muk.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Sanandaj University of Medical Sciences

Full name of responsible person

Afshin Maleki

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Web page address**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Sanandaj University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Sanandaj University of Medical Sciences

Full name of responsible person

Soma Arabzade Moghadam

Position

assistant professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

Soma Arabzade Moghadam

Position

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Latest degree

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Person responsible for updating data

Contact

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Full name of responsible person

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Fax**Email**

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Data included 1- The age of the participants and their gender 2. The number of pain felt by the participants 3. Hypnosis method

When the data will become available and for how long

4 month after printing the article

To whom data/document is available

All researchers in the field of psychology and dentistry

Under which criteria data/document could be used

To research the subject of study

From where data/document is obtainable

Email to Dr. Fayegh yousefi via fykmsu@gmail.com Dr. Soma Arabzadeh Moghadam via s.arabzade@muk.ac.ir

What processes are involved for a request to access data/document

1. Send emails to people who have been identified. 2. Review the request by the individuals who have been identified. 3- Permission to access the data if you have the conditions (maximum 14 days from the time of sending the email)

Comments