

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

18 Sep 2026

### The effect of video games on self assessment and reaction to pain during anesthesia injection of lower alveolar nerve block in children 6 to 9 years

#### Protocol summary

##### Study aim

The effect of video games on self assessment and reaction to pain during anesthesia injection of lower alveolar nerve block in children 6 to 9 years.

##### Design

The present study is a one-way randomized controlled clinical trial. Using the sample size formula, 17 people in each group were calculated. It should be noted that the researcher increased the number of samples to 30 people in each group to increase the accuracy of the study. Children are selected by available sampling method. Children from 6 to 9 years old are assigned to the control group and the distraction group based on the random number table.

##### Settings and conduct

The present study is a single-blind randomized controlled clinical trial. The statistical population includes 60 children referred to the pediatric dentist's office. The ACC and Wong-Baker FL are measured during injection.

##### Participants/Inclusion and exclusion criteria

Children without previous experience with LA in dentistry  
No gag reflex  
Participants in the study are children 6-9 years old. Patients , who needed dental treatment in lower arch  
Patients , who needed anesthesia injection of lower alveolar nerve block  
The presence of parents with the child. Not having verbal and auditory disorders, absence of acute and chronic diseases  
Having the ability to communicate;

##### Intervention groups

The vote of both groups uses a standard text to create verbal distraction. For the main injection, a 2% carpolidocaine containing 1.80000pinephrine will be used. For the intervention group, 5 minutes before the lower alveolar nerve block anesthesia injection, the distraction process begins with a video game on a mobile phone given to the subjects. . The video game used was related to SEGA's Sonic series games.

##### Main outcome variables

reaction to pain during anesthesia injection

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20201124049479N1**

Registration date: **2021-08-16, 1400/05/25**

Registration timing: **retrospective**

Last update: **2021-08-16, 1400/05/25**

Update count: **0**

##### Registration date

2021-08-16, 1400/05/25

##### Registrant information

##### Name

Azam Nahvi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 11 3326 5176

##### Email address

a.nahvi@mazums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-12-10, 1399/09/20

##### Expected recruitment end date

2021-03-10, 1399/12/20

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of video games on self assessment and reaction to pain during anesthesia injection of lower alveolar nerve block in children 6 to 9 years

**Public title**  
The effect of video games on self assessment and reaction to pain during anesthesia injection of lower alveolar nerve block in children 6 to 9 years

**Purpose**  
Supportive

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Children without previous experience with LA in dentistry  
No gag reflex Participants in the study are children 6-9 years old. Patients , who needed dental treatment in lower arch Patients , who needed anesthesia injection of lower alveolar nerve block The presence of parents with the child. Not having verbal and auditory disorders, absence of acute and chronic diseases Having the ability to communicate;  
**Exclusion criteria:**

**Age**  
From **6 years** old to **9 years** old

**Gender**  
Both

**Phase**  
N/A

**Groups that have been masked**

- Data analyser

**Sample size**  
Target sample size: **60**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
Children are assigned individually to the control group and distraction group based on a table of random numbers by simple randomization method.

**Blinding (investigator's opinion)**  
Single blinded

**Blinding description**  
Data Analyzer The person who analyzed the data collected during the study was blinded by coding the study groups.

**Placebo**  
Not used

**Assignment**  
Parallel

**Other design features**

**Secondary Ids**  
empty

**Ethics committees**

**1**

**Ethics committee**  
**Name of ethics committee**  
Ethics committee of Mazandaran University of Medical Sciences

**Street address**  
Caspian Boulevard

**City**  
Sari

**Province**  
Mazandaran

**Postal code**  
48157339710

**Approval date**  
2020-08-31, 1399/06/10

**Ethics committee reference number**  
1399.567

**Health conditions studied**

**1**

**Description of health condition studied**  
Anesthesia injection of the lower alveolar nerve block

**ICD-10 code**

**ICD-10 code description**

**Primary outcomes**

**1**

**Description**  
reaction to pain during anesthesia injection

**Timepoint**  
in intervention

**Method of measurement**  
FLACC scale-Wong-Baker

**Secondary outcomes**  
empty

**Intervention groups**

**1**

**Description**  
Intervention group: For the intervention group, 5 minutes before the anesthetic injection of the inferior alveolar nerve block, the process of creating distraction begins with a video game on a mobile phone that is given to the subjects. At the end of the injection and before starting occupational therapy, the subjects can use the game. The video game used is related to the Sonic series games from SEGA company

**Category**  
Behavior

**2**

**Description**  
Control group: For initial mucosal anesthesia, a cotton ball soaked in 20% topical benzocaine gel is used for 30 seconds 30 seconds after drying the mucosa with a sterile gauze. For the main injection, a 2% carpol lidocaine containing 1.8000pinephrine (Daroo Pakhsh, Tehran, Iran) and a needle with a 27 gauge are used.

**Category**  
Behavior

**Type of organization providing the funding**  
Academic

## Recruitment centers

1

### Recruitment center

**Name of recruitment center**  
Dental Clinic of Dr. Nahvi  
**Full name of responsible person**  
Azam Nahvi  
**Street address**  
Farhang Ave, 15 Khordad Ave.  
**City**  
Sari  
**Province**  
Mazandaran  
**Postal code**  
4816895475  
**Phone**  
+98 11 3325 4135  
**Email**  
Azamnahvi.pedodontist@gmail.com

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**  
Mazandaran University of Medical Sciences  
**Full name of responsible person**  
Majid Saidi  
**Street address**  
Khazar Blvd.  
**City**  
Sari  
**Province**  
Mazandaran  
**Postal code**  
4816895475  
**Phone**  
+98 11 3325 4135  
**Email**  
azamnahvi.pedodontist@gmail.com

### Grant name

### Grant code / Reference number

### Is the source of funding the same sponsor organization/entity?

Yes

### Title of funding source

Mazandaran 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

## Person responsible for general inquiries

### Contact

**Name of organization / entity**  
Mazandaran University of Medical Sciences  
**Full name of responsible person**  
Azam Nahvi  
**Position**  
Assistant professor  
**Latest degree**  
Specialist  
**Other areas of specialty/work**  
Dentistry  
**Street address**  
Khazar Blvd.  
**City**  
Sari  
**Province**  
Mazandaran  
**Postal code**  
4816895475  
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**Email**  
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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Mazandaran University of Medical Sciences  
**Full name of responsible person**  
Azam Nahvi  
**Position**  
Assistant professor  
**Latest degree**  
Specialist  
**Other areas of specialty/work**  
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**Email**  
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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Mazandaran University of Medical Sciences  
**Full name of responsible person**

Azam Nahvi

**Position**

Assistant professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Dentistry

**Street address**

Khazar Blvd.

**City**

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**Province**

Mazandaran

**Postal code**

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**Phone**

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**Email**

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## Sharing plan

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

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Not applicable

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Not applicable

**Analytic Code**

Not applicable

**Data Dictionary**

Not applicable