

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

21 Jul 2026

### The influence of virtual reality eye glasses on severity of pain and anxiety during inferior alveolar nerve block in 6-8 age children

#### Protocol summary

##### Summary

To determine the effect of Audio Visual eyeglasses system on severity of pain and anxiety during dental injection, a double blinded crossover clinical trial was done over 40 healthy children; aged between 6 to 8 years old. Children having the inclusion criteria were coded and by using website [www.randomizer.org](http://www.randomizer.org) randomly allocated into two groups (each group consisted of 20 children). The study was done during 3 continuance sessions. At the first visit prophylaxis & fluoride therapy was done for both two groups. Next session the first group used an audiovisual eyeglasses system during dental treatment & the second group underwent injection with no intervention. During last session injection was done with no intervention for first group but by using Audiovisual eyeglasses for second group. All the injections were done by a resident of paediatric dentistry. Then at the end of each session subjects' pain severity was assessed, with pictorial VAS scale (visual Analogue Scale) & situational anxiety measured by Modified Child Dental Anxiety Scale (MCDAS).

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201103126036N1**

Registration date: **2011-04-28, 1390/02/08**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2011-04-28, 1390/02/08

##### Registrant information

Name

Armaghan Naghili

##### Name of organization / entity

Tabriz dental faculty

##### Country

Iran (Islamic Republic of)

##### Phone

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##### Email address

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##### Recruitment status

**Recruitment complete**

##### Funding source

Tabriz University of Medical Sciences

##### Expected recruitment start date

2010-04-17, 1389/01/28

##### Expected recruitment end date

2010-06-21, 1389/03/31

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The influence of virtual reality eye glasses on severity of pain and anxiety during inferior alveolar nerve block in 6-8 age children

##### Public title

The influence of virtual reality eye glasses on severity of pain and anxiety during inferior alveolar nerve block in 6-8 age children

##### Purpose

Supportive

##### Inclusion/Exclusion criteria

The selected cases should have no systemic diseases such as bleeding problems, and mental disabilities.  
inclusion criteria: Existence of carious primary molars necessitating administration inferior alveolar nerve block

anaesthesia, have no Previous experience of intra oral injection, have no allergy to Lidocaine, have no History of pain secondary to pulpitis favouring a biased context due to special pain status such as hyperalgesia or allodynia, have no History of unpleasant experiences in medical settings, have no mental, psychological and behaviour problems, absence of childhood anxiety related disorders, SCARED questionnaire score > 25

**Age**

From **6 years** old to **8 years** old

**Gender**

Both

**Phase**

1-2

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **40**

**Randomization (investigator's opinion)**

Randomized

**Randomization description****Blinding (investigator's opinion)**

Double blinded

**Blinding description****Placebo**

Not used

**Assignment**

Crossover

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Tabriz University of Medical Sciences, Tabriz Dental Faculty

**Street address**

Tabriz, Golgasht st.

**City**

Tabriz

**Postal code****Approval date**

2010-11-21, 1389/08/30

**Ethics committee reference number**

8951

**Health conditions studied****1****Description of health condition studied**

situational anxiety

**ICD-10 code**

f93.8

**ICD-10 code description**

Emotional disorders with onset specific to childhood  
, Other childhood emotional disorders

**2****Description of health condition studied**

pain(tooth pain)

**ICD-10 code**

k08.8

**ICD-10 code description**

Other specified disorders of teeth and supporting structures, Toothache NOS

**Primary outcomes****1****Description**

pain during dental injection

**Timepoint**

Immediately after injection

**Method of measurement**

pictorial VAS (Visual Analogue Scale)

**Secondary outcomes****1****Description**

situational anxiety during dental injection

**Timepoint**

immediately after injection

**Method of measurement**

MCDAS (Modified Children Dental Anxiety Scale)

**Intervention groups****1****Description**

The intervention group: used an audiovisual eyeglasses system during dental treatment (the eyeglasses system showed TOM & GERRY cartoon for children)

**Category**

Behavior

**2****Description**

The control group: underwent injection with no intervention

**Category**

N/A

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Tabriz Dental Faculty

**Full name of responsible person**

Dr. Naser Asl Aminabadi

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**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Dr. Alireza Ostad Rahimi

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Vice chancellor for Research, Tabriz University of Medical Sciences, Daneshgah Ave.

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

Yes

**Title of funding source**

Tabriz University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector***empty***Domestic or foreign origin***empty***Category of foreign source of funding***empty***Country of origin****Type of organization providing the funding***empty***Person responsible for general inquiries****Contact****Name of organization / entity**

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last year dentistry student

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**Web page address****Sharing plan****Deidentified Individual Participant Data Set (IPD)***empty***Study Protocol***empty***Statistical Analysis Plan***empty***Informed Consent Form***empty***Clinical Study Report***empty***Analytic Code***empty*

