

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jul 2026

Evaluation of the effect of clinician-patient relationship protocol on vital signs control (Heart Rate, Blood Pressure) in emergency endodontic patients

Protocol summary

Study aim

Determination of the effect of clinician-patient relationship protocol on controlling vital sign(Heart Rate, Blood Pressure) in emergency endodontic patients

Design

Randomized clinical trial with control group, with single blinded parallel group

Settings and conduct

60 emergency patients referred to endodontic department of dental school Shahid Sadoughi University of Medical Sciences with the age range between 18-65 will be participated in the present study. Vital signs (BP,HR) will be recorded in the four stages: immediately before the treatment, during the anesthesia injection, during tooth preparation and ultimately before the patient discharge. In the control group the clinician will treat the patients without any communication and reduced anxiety protocol and in the case group during the treatment the patient-clinician relationship protocol will be applied.

Participants/Inclusion and exclusion criteria

Inclusion criteria:Age range18-65 , presence of preoperative pain Exclusion criteria:Patients below 18 yrs, pregnant, patients with hypertension and any drug consumption with interaction with hypertension , patients with systemic diseases

Intervention groups

In the case group patient relationship protocol will be applied and in the control group treatment will be done without intervention.

Main outcome variables

patient-clinician relationship protocol ,blood pressure, heart rate

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150318021507N2**

Registration date: **2018-07-30, 1397/05/08**

Registration timing: **prospective**

Last update: **2018-07-30, 1397/05/08**

Update count: **0**

Registration date

2018-07-30, 1397/05/08

Registrant information

Name

Maryam Kazemipoor

Name of organization / entity

Dental school

Country

Iran (Islamic Republic of)

Phone

+98 35 3625 5881

Email address

m.kazemipoor@ssu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-09-01, 1397/06/10

Expected recruitment end date

2018-11-11, 1397/08/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of clinician-patient relationship protocol on vital signs control (Heart Rate, Blood Pressure) in emergency endodontic patients

Public title

Evaluation of the effect of clinician-patient relationship protocol on vital signs control

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Age range 18-65 presence of preoperative pain

Exclusion criteria:

patients below 18 yrs pregnant patients with hypertension and any drug consumption with interaction with hypertension patients with systemic diseases

Age

From **18 years** old to **65 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

According to random table ,patients will be assigned to the two control and case groups. Randomization is a fallows: All the participant will be asked to select a number between 1-120 and according to random table they will be assinged into control or case group. Then the secretary will inform the clinician of the assigned groups to accomplish the treatment and intervention based on the related group.

Blinding (investigator's opinion)

Single blinded

Blinding description

Data analyser is not aware of the intervention procedure (clinician-patient relationship protocol).

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shahid Sadoughi university of medical sciences

Street address

Emam Reza Blvd, Emam Reza Square, Dental School, Yazd, Iran

City

Yazd

Province

Yazd

Postal code

8914881167

Approval date

2018-05-20, 1397/02/30

Ethics committee reference number

IR.SSU.REC.1397.012

Health conditions studied

1

Description of health condition studied

Emergency endodontic diseases

ICD-10 code

K04

ICD-10 code description

Diseases of pulp and periapical tissues

Primary outcomes

1

Description

Clinician-patient relationship protocol

Timepoint

will be recorded in the four stages: immediately before the treatment, during the anesthesia injection, during tooth preparation and ultimately before the patient discharge

Method of measurement

Digital Sphygmomanometer OMRON

Secondary outcomes

1

Description

Blood pressure and Heart Rate

Timepoint

four stages: immediately before the treatment, during the anesthesia injection, during tooth preparation and ultimately before the patient discharge

Method of measurement

OMRON Digital Sphygmomanometer

Intervention groups

1

Description

Intervention group: Root canal treatment with intervention of clinician - patient relationship: Having a calm manner, Saying reassuring things, taking seriously telling the patient what was to be done, encouraging the patient to ask questions, not to criticize the patient

Category
Behavior

2

Description

Control group: Root canal treatment without intervention of clinician - patient relationship: Having a calm manner, Saying reassuring things, taking seriously telling the patient what was to be done, encouraging the patient to ask questions, not to criticize the patient

Category
Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center
Dental school, Shahid Sadoughi University of Medical Sciences, Yazd

Full name of responsible person
Maryam Kazemipoor

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Emam Reza Blvd, Emam Reza Square, Dental School, Yazd, Iran

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dr.kazemipoor@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice Chancellor For research,Shahid Sadoughi University of Medical Scieces

Full name of responsible person
Dr.Masood Mirzaei

Street address
Shahid Sadoughi university of medical sciences, Bahonar square, Yazd

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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

Vice Chancellor For research,Shahid Sadoughi University of Medical Scieces

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
Yazd University of Medical Sciences

Full name of responsible person
Maryam Kazemipoor

Position
Associate professor

Latest degree
Specialist

Other areas of specialty/work
Dentistry

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Person responsible for scientific inquiries

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Person responsible for updating data

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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

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

Informed Consent Form

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

Clinical Study Report

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

Analytic Code

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

Data Dictionary

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