

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of using physics forceps and conventional forceps on post tooth extraction complication

Protocol summary

Study aim

Investigating the effect of forceps physics on complications after tooth extraction.

Design

This study is clinical trial. 26 patients at Arak Dental School are divided into two groups of 13 subjects. They are divided into standard and intervention groups. This study is double blind. Participant and analyzer are blind (double blind). Participant and analyzer don't aware from grouping.

Settings and conduct

26 patients at Arak Dental School are included in two groups of 13 subjects. This study is double blind. Participant and analyzer are blind (double blind). Participant and analyzer don't aware from grouping.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 18 to 45 years of both sexes: ASA I and II: the teeth have 3 millimeters of healthy structure: they do not have a local anesthetic :not pregnant: not have periodontal disease: not need an orthodontic: no residual root: Do not have abnormal teeth. Exclusion criteria: Persons who do not have the consent to continue studying for any reason

Intervention groups

Sample group: Tooth extraction with physics forceps. Standard group: extraction with conventional forceps and elevator. Forceps Physics Group: Injection of numbness and separation of the gums from the tooth

Main outcome variables

Time for extraction: Root fracture :Crown Fracture: buccal cortical plate fracture: soft tissue laceration

Registration date: **2019-01-08, 1397/10/18**

Registration timing: **retrospective**

Last update: **2019-01-08, 1397/10/18**

Update count: **0**

Registration date

2019-01-08, 1397/10/18

Registrant information

Name

Fatemeh Shadorvan

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 86 3313 6055

Email address

fatemeh.shadorvan@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-08-03, 1397/05/12

Expected recruitment end date

2018-10-12, 1397/07/20

Actual recruitment start date

2018-08-11, 1397/05/20

Actual recruitment end date

2018-10-21, 1397/07/29

Trial completion date

2018-10-21, 1397/07/29

Scientific title

Comparison of using physics forceps and conventional forceps on post tooth extraction complication

Public title

Comparison of using physics forceps and conventional forceps on post tooth extraction complication

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181211041933N1**

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Those who are ASA (American Association of Anesthesiologists) are classified in the I-II Group according to the ASA (*) table. People whose teeth have a thickness of 3 mm or more and have a healthy structure above the gingival margin level. People who do not have a local anesthetic prescription. People who do not have dental periodontal disease or not have a soft, hard tissue around the teeth. Those who do not need to remove the tooth for orthodontic treatment. People who do not have the roots left. Women who are not pregnant or not Postmenopausal. Persons with abnormal dental roots (severe or felonous roots, hyperthermosis roots or internal or external analysis, etc.) 18-45 years

Exclusion criteria:

Persons who do not have the consent to continue studying for any reason

Age

From **18 years** old to **45 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **28**

Actual sample size reached: **26**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple individual randomization with random number in division of groups in two groups A and B. Randomized patients are divided into two groups. Randomized allocation in clinical trial studies refers to the process of dividing participants into different groups randomly. Randomizing gives each participant equal odds for being placed in each of the groups. The candidate patients who enter the study are randomly assigned to the randomly assigned table of randomly assigned to the two groups. Individual

Blinding (investigator's opinion)

Double blinded

Blinding description

This study is double blind. Participant and analyzer are blind (double blind). Participant and analyzer don't aware from grouping

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of the University of Medical Sciences and Health Services of Markazi Province (Arak)

Street address

Shahid Shiroudi Ave., Aalam-e Hoda St., Arak
University of Medical Sciences and Health Services

City

Arak

Province

Markazi

Postal code

3819693345

Approval date

2018-08-19, 1397/05/28

Ethics committee reference number

IR.ARAKMU.REC.1397.135

Health conditions studied

1

Description of health condition studied

Teeth extraction

ICD-10 code

K02.7

ICD-10 code description

Dental root caries

Primary outcomes

1

Description

Number of broken roots after tooth extraction

Timepoint

after of tooth extraction

Method of measurement

Radiographic image

2

Description

Percentage of broken crowns after tooth extraction

Timepoint

After of tooth extraction

Method of measurement

Radiographic image

3

Description

Percentage of fracture of buccal plate after tooth

extraction
Timepoint
after of tooth extraction
Method of measurement
Clinical and radiographic images

Secondary outcomes

1

Description
Time to tooth extraction
Timepoint
Start extraction until the end of the process
Method of measurement
stopwatch

2

Description
Gingival after tooth extraction
Timepoint
After tooth extraction
Method of measurement
Clinical, observation

Intervention groups

1

Description
Intervention group: Forceps Physics whose tool for extraction teeth, making Dana Poya , non-usable, usable for more times and sterilized
Category
Treatment - Devices

2

Description
Control group: conventional forceps,for tooth extraction, manufacture of Joya Company, can be used frequently and sterilized, non-consumable
Category
Treatment - Devices

Recruitment centers

1

Recruitment center
Name of recruitment center
Dental clinic
Full name of responsible person
fatemeh shadorvan
Street address
Shahid Shiroodi Ave.sardasht,Masomeh's dormitory
City
Arak
Province
Markazi
Postal code

3819693345
Phone
+98 61 3333 8621
Email
fatemeh.shadorvan@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Mojtaba Bayani
Street address
Payambar Azam Complex, Basij square, Sardasht, Arak
City
Arak
Province
Markazi
Postal code
3848153793
Phone
+98 86 3275 4523
Email
mbayani@mail.com
Web page address
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Arak 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
Arak University of Medical Sciences
Full name of responsible person
Seyed behrouz jalali
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
Dentistry
Street address

Payamuare, Sardasht, Arakbar Azam Complex, Basij
sq

City

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3819736355

Phone

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Email

behrouzjalali@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Behrouz Jalali

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Oral and Maxillofacial Surgery

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Payambar Azam Complex, Basij square, Sardasht,
Arak

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3819736355

Phone

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Email

behrouzjalali@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Fatemeh Shadorvan

Position

student

Latest degree

A Level or less

Other areas of specialty/work

Dentistry

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fatemeh.shadorvan@yahoo.com

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

Undecided - It is not yet known if there will be 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

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

Title and more details about the data/document

Part of the data, such as information on the main
outcome, and the possibility of result sharing.

**When the data will become available and for how
long**

Get started 1 month after printing results

To whom data/document is available

All people who work in academia, science and industry

Under which criteria data/document could be used

All people who need to use content and analysis. All
researchers and students in dentistry and medicine. It
can be used in all theses and proposals and articles.

From where data/document is obtainable

fatemeh.shadorvan@yahoo.com tell number
09166147318

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

Email will be sent at least one week after the request.

Comments