

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jun 2026

Evaluation of complementary subgingival irrigation on the periodontal health in the management of jaw and dentoalveolar fracture using arch bar and dentoalveolar wiring

Protocol summary

Summary

arch bar is the most predictable way to manage maxillofacial fracture but it has some complications. wires cause plaque accumulation and also oral hygiene control is challenging because of circum dental wiring, arch bar and gingival ulcers. these problems cause gingivitis, mal odor during the arch bar treatment. Therefore, in this study we are adding periodically removal of plaque with subgingival washing by jet irrigator during fracture treatment, and evaluate its impact on reducing harmful effect of Arch Bar on Preiodontiom such as gingival ulcers, malodor (which is a common complaint of patients), and increased tooth mobility and pocket depth. According to the same articles, sample size is 60 patients. patients with mandibulomaxillary or dentoalveolar fracture and are referred to maxillofacial ward of bahonar hospital are selected. Patients who have treatment plan that is include open reduction and fixation with 10 days intermaxillary fixation (IMF) are remain in the study. patients will be divided in two groups (A, B) with even and odd method. A clinician to perform an initial check and supplementary examinations will be trained. Patients will be examined before surgery by this clinicians who is blind to this research (the probing depth and panoramic radiography will be done). oral Health care recommendations for all patients during treatment will be carried out. patients in group A will have sub gingival irrigation with chlorhexidine 2 times a week and dental care recommendation. patient in group B will have only oral hygiene recommendation. after 2 month arch bar will be removed and these examination will be done for the patients with the clinician that the primary examination had done by him and is blind to this research: 1- tooth mobility 2- plaque index 3- gingival index 4- extended and severity index

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017032232354N2**
Registration date: **2017-06-28, 1396/04/07**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-06-28, 1396/04/07

Registrant information

Name

Sorena Fardisi

Name of organization / entity

Kerman University of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 32123965

Email address

s.fardisi@kmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Kerman University of Medical Science

Expected recruitment start date

2017-03-21, 1396/01/01

Expected recruitment end date

2018-04-22, 1397/02/02

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of complementary subgingival irrigation on the periodontal health in the management of jaw and dentoalveolar fracture using arch bar and dentoalveolar wiring

Public title

Evaluation of complementary subgingival irrigation on the **الهدلهرشم** health in the management of jaw fracture using dentoalveolar wiring

Purpose

Supportive

Inclusion/Exclusion criteria

inclusion criteria: patient are selected from whom that have mandibular or maxillary fracture and referred to maxillofacial ward of bahonar hospital. exclusion criteria: patient who are not dentated in upper and lower jaws that arch bar treatment was done; patient with periodontitis; their treatment plan is not included open reduction rigid fixation and 10 days intermaxillary fixation with arch bar

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

kerman University of Medical Sciences

Street address

Dental school, Shafa street

City

Kerman

Postal code

00987618759689

Approval date

2010-09-23, 1389/07/01

Ethics committee reference number

IR.KMU.REC.1395.759

Health conditions studied

1

Description of health condition studied

periodontitis

ICD-10 code

k05.4

ICD-10 code description

periodontosis

Primary outcomes

1

Description

dental mobility

Timepoint

after arch bar removal

Method of measurement

colis

2

Description

gigiva inflamation

Timepoint

after arch bar removal

Method of measurement

gingival index loe and silness

3

Description

plaque aqumilation

Timepoint

after arch bar removal

Method of measurement

plaque index silnessand loe

4

Description

periodontitis

Timepoint

after arch bar removal

Method of measurement

ESI index

Secondary outcomes

empty

Intervention groups

1

Description

oral hygien recommendation and subgingival irrigation during fracture treatment

Category

Prevention

2

Description

oral hygiene recommendation in the control group during the fracture treatment

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Bahonar hospital

Full name of responsible person

Dr Sorena Fardisi

Street address

Shariatee Street

City

Kerman

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Dr Sorena Fardisi

Street address

Kerman

City

Kerman

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Kerman 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

Kerman University of Medical Sciences

Full name of responsible person

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Position

Maxillofacial surgeon

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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

Data Dictionary

empty