

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Jul 2026

The effect of Calcium Alginate dressing on bleeding and complications after tooth extraction socket

Protocol summary

Study aim

Determination of the effect of Calcium Alginate dressing on bleeding and complications after tooth extraction in patients referred to Oral and maxillofacial surgery department of dental faculty, Islamic Azad University, Tehran, 1395-96

Design

This clinical trial, split mouth study will be done on 30 patients and 60 samples, referred to Department of Oral and Maxillofacial Surgery, Faculty of Dentistry, Tehran, Iran, Which will have an indication of simple bilateral tooth extraction in a one jaw, and do not have exclusion criteria (such as: complexity during tooth extraction, need to suturing and systemic disease). Two socket in each jaw are randomly divided into two groups of control and case group.

Settings and conduct

This study will be done on, 20-60 years patients that referred to department of oral and maxillofacial surgery, faculty of dentistry, Tehran, Iran, Which will have an indication of simple bilateral tooth extraction in a one jaw. Each tooth socket will be divided randomly into case and control groups. In the control group, conventional gas and in the case group Calcium Alginate dressing will be placed. Then, both groups will be evaluated from the amount of bleeding and other complications after extraction of the tooth in one day, three days and seven days after the operation. In this study blindness will not be performed.

Participants/Inclusion and exclusion criteria

Inclusion criteria; Indication of simple bilateral tooth extraction in one jaw. Exclusion criteria; patients with Systemic Diseases; Patients aged less than 20 and over 60 years; Teeth that require flap surgery to remove; Need to use sutures at the treatment site; Things that delay the tissue healing, including: excessive trauma during teeth removal; History of allergy to the drugs used in the study; Absence of referral for re-examination by the patient

Intervention groups

The control group; The tooth Socket that will be dressed by conventional gas. The case group; The tooth Socket that will be dressed by Calcium Alginate.

Main outcome variables

In this study, variables: bleeding, one hour and 24 hours after operation and healing, pain and dry socket on the third and seventh day after surgery will be assessed. It is expected that; Using the dressing of calcium alginate, the amount of bleeding, dry socket and post operative pain will decrease; and tissue healing will increase.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171216037893N1**

Registration date: **2018-01-29, 1396/11/09**

Registration timing: **registered_while_recruiting**

Last update: **2018-01-29, 1396/11/09**

Update count: **0**

Registration date

2018-01-29, 1396/11/09

Registrant information

Name

Hamidreza Mahaseni aghdam

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2240 6440

Email address

h_mahaseni@dentaliau.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-01-21, 1396/11/01

Expected recruitment end date

2018-02-20, 1396/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Calcium Alginate dressing on bleeding and complications after tooth extraction socket

Public title

The effect of Calcium Alginate dressing on bleeding and complications after tooth extraction socket

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Indication of simple bilateral tooth extraction in one jaw

Exclusion criteria:

patients with systemic diseases Patients aged less than 20 and over 60 years Teeth that require flap surgery to remove Need to use sutures at the treatment site Things that delay the tissue healing, including: excessive trauma during teeth removal History of allergy to the drugs used in the study Absence of referral for re-examination by the patient

Age

From **20 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked*No information***Sample size**

Target sample size: **30**

More than 1 sample in each individual

Number of samples in each individual: **2**

A dental socket after removing it on one side of the jaw

Randomization (investigator's opinion)

Randomized

Randomization description

Simple Random Sampling individually with using random numbers

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

This study is split mouth

Secondary Ids

empty

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

Ethics committee of Islamic Azad University of Medical Sciences

Street address

No.4,Thens Neyestan,Pasdaran street

City

Tehran

Province

Tehran

Postal code

19486

Approval date

2017-09-24, 1396/07/02

Ethics committee reference number

IR.IAU.DENTAL.REC.1396/23

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

Indication of simple bilateral tooth extraction in one jaw

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Bleeding ;

Timepoint

one hour and 24 hours after surgery

Method of measurement

placement of the gas on tooth socket every 15 seconds until the stain of blood do not get bigger

2**Description**

Dry socket

Timepoint

the third and seventh day after surgery

Method of measurement

BLUM scale

3**Description**

pain

Timepoint

the third and seventh day after surgery

Method of measurement

VAS scale

4

Description

Healing

Timepoint

the third and seventh day after surgery

Method of measurement

Healing scale

Secondary outcomes

empty

Intervention groups

1

Description

" Case group"; The tooth Socket that will be dressed by Calcium Alginate.

Category

Treatment - Devices

2

Description

"Control group": The tooth Socket that will be dressed by conventional gas.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Faculty of Dentistry, Azad University of Medical Sciences, Tehran, Iran

Full name of responsible person

Dr Hamid Reza Mahaseni Aghdam

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Sponsors / Funding sources

1

Sponsor

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Personal

Full name of responsible person

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Grant name

Nothing

Grant code / Reference number

ندارد

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

Yes

Title of funding source

Personal

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

Islamic Azad University

Full name of responsible person

Hamid Reza Mahaseni Aghdam

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

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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