Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Evaluation of Gelatamp effectivness on pain and bleeding after teeth extraction

Protocol summary

Summary

(1) Objective: This study will conduct to investigate the effect of Gelatamp on pain and gingival bleeding after extraction of teeth. (2) Design: This study is a single center double blind randomized controlled clinical trial. (3) Setting and conduct: This study will conduct in Dental clinic of Qom School of Dentistry. After tooth extraction surgery will use Gelatamp dressing for eligible patients and compare with routine dressing with sterile gauze. (4) Participants including major eligibility criteria: This clinical trial will carry out on 71 patients of both sex, aged 20-45 years who refer for extraction of their two teeth in same location in maxillary or mandibular gingiva. (5) Intervention: After teeth extraction randomly the Geltamp will use in one site and sterile gauze in the other site for dressing. (6) Main outcome measures: Active bleeding will monitor every five minutes until cessation of bleeding and one hour after that. Also pain will measure every six hour for 48 hour.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015113025303N1**
Registration date: **2015-12-30, 1394/10/09**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2015-12-30, 1394/10/09

Registrant information

Name

Pooya Piri

Name of organization / entity

Qom University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Email address

dr_pooyapiri@yahoo.com

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research of Qom University of Medical Sciences

Expected recruitment start date

2015-12-06, 1394/09/15

Expected recruitment end date

2016-01-21, 1394/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of Gelatamp effectivness on pain and bleeding after teeth extraction

Public title

The effect of Geltamp on teeth extraction complications

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Age between 20-45 years; No sensitivity to silver; Not using corticosteroid; antibiotic and anticoagulant within the past month; Not having clotting disorder; No acute or uncontrolled infection at the surgery site; No malignancy at the surgery site; No history of exposure of surgery site to radiation; Not using contraceptive drug over the past month; Not smoking; Not having hypertension, diabetes, thyroid disorder and blood disorder. Exclusion criteria: No readmission for

second tooth extraction; Failure to complete postoperative; Using of out of prescription drugs; Discontinuation of participation in the study; Developing a systemic disease.

Age
From **20 years** old to **45 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **71**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
In this study, random allocation between the two groups will be done by using a random numbers table.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Qom University of Medical Sciences

Street address
No 83, Alley No 4, Alley No 1/1, Safashahr, Qom

City
Qom

Postal code

Approval date
2015-11-11, 1394/08/20

Ethics committee reference number
IR.MUQ.REC.1394.126

Health conditions studied

1

Description of health condition studied
Bleeding

ICD-10 code
R58

ICD-10 code description
Haemorrhage NOS

2

Description of health condition studied
Pain

ICD-10 code
R52

ICD-10 code description
Acute pain

Primary outcomes

1

Description
Bleeding

Timepoint
Every Five Minutes until Stop of Bleeding

Method of measurement
Minute by Timer

Secondary outcomes

1

Description
Pain

Timepoint
Every Six Hour for 48 Hour

Method of measurement
Visual Analog Scale

Intervention groups

1

Description
Intervention group: Using of one Geltamp in dental socket after tooth extraction Gelatamp is made of 95% foam gelatin sponge and 5% finely dispersed colloidal silver. In this study will use Gelatamp manufactured by Coltene Company in Germany

Category
Prevention

2

Description
Control group: Using of routine dressing with sterile gauze after tooth extraction

Category
Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center
Shcool of Dentistry Dental Clinic

Full name of responsible person

Street address
Shahid Lvasani Street, School of Dentistry,

Educational Complex of Qom University of Medical Sciences, Qom

City
Qom

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice Chancellor for research of Qom University of Medical Sciences

Full name of responsible person
Mohammad Hoessein Abdolmohamdi

Street address
No 83, Alley No 4, Alley No 1/1, Safashahr, Qom

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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 of Qom 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
Qom University of Medical Sciences

Full name of responsible person
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Position
Dentist

Other areas of specialty/work

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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