

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of analgesic and anti-inflammatory effect of topical application of ginger aqueous extract with local dexamethasone injection after extraction of mandibular wisdom teeth

Protocol summary

Summary

The aim of this study was to compare the analgesic and anti-inflammatory effects of topical application of ginger aqueous extract and local dexamethasone injection after extraction of mandibular wisdom. The aim of this study was to facilitate supportive care and reduce the complications of dexamethasone and analgesics. Design of the study: Interventional, non-random, non-randomly assigned to intervention and control, with placebo, parallel intervention groups. Main criteria for entering the study: having the same wisdom teeth in the mandible and the desire to remove both, general health criteria. Main outcomes: Incompatibility and sensitivity to any of the drugs used in the study. Blindness: For the patient: In the place where the ginger bioadhesive, after removing the tooth, one carpool of lidocaine anesthetic is injected as a placebo. Also, in the tooth extraction of the other side, which 1.8 ml of dexamethasone 1.6 mg is injected, base bioadhesive (without ginger) is used. For researcher: After removing the tooth and using the appropriate medication and placebo by surgeon, the researchers provided the patient with post-discharge explanations. Therefore, this study was blind to the patient and researcher. In fact, only the surgeon knows what medicine he has used. The researcher and patient do not know.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017082635906N1**

Registration date: **2017-09-09, 1396/06/18**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-09-09, 1396/06/18

Registrant information

Name

sahar zandi

Name of organization / entity

Bushehr University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 77 3356 5374

Email address

s.zandi@bpums.ac.ir

Recruitment status

Recruitment complete

Funding source

Investigator

Expected recruitment start date

2017-09-06, 1396/06/15

Expected recruitment end date

2017-11-06, 1396/08/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of analgesic and anti-inflammatory effect of topical application of ginger aqueous extract with local dexamethasone injection after extraction of mandibular wisdom teeth

Public title

Study of analgesic and anti-inflammatory effect of ginger

Purpose

Supportive

Inclusion/Exclusion criteria
 Inclusion criteria: The patient has a double-walled tooth (based on the angle of tooth placement in the jaw, the amount of bone and soft tissue on the tooth, the condition of the tooth in relation to the anterior border of ramus), the willingness to cooperate And there is no prohibition of tooth surgery or sensitivity to ginger. The tooth does not have any pathological lesions in the root zone in clinical and radiographic examinations. No other surgical procedures for at least two weeks. Exclusion criteria: kidney or liver disease, bleeding problems such as hemophilia, neutropenia, blood platelet deficiency, etc., previous or current stomach ulcers, any heart disease, Known allergies, allergies, or individual reactions to either the drugs used or the drugs that may be used in the study (ginger, lidocaine anesthesia, acetaminophen codine 300, gelofen 400, amoxicillin 500, and metronidazole 400 mg G) Pregnancy and lactation, taking analgesic or anti-inflammatory drugs 24 hours before the study, having pain and other inflammatory symptoms including swelling, high blood pressure and the inability to open the mouth before the study.

Age
 No age limit

Gender
 Both

Phase
 N/A

Groups that have been masked
 No information

Sample size
 Target sample size: 50

Randomization (investigator's opinion)
 Not randomized

Randomization description

Blinding (investigator's opinion)
 Double blinded

Blinding description

Placebo
 Used

Assignment
 Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

The Ethics Committee of the Vice-Chancellor of
 Research of Bushehr University of Medical Sciences

Street address

Imam Khomeini Ave (Bushehr), Bushehr University of
 Medical Sciences, Faculty of Dentistry

City

Bushehr

Postal code
Approval date
 2016-05-14, 1395/02/25
Ethics committee reference number
 IR.BPUMS.REC.1396.36

Health conditions studied

1

Description of health condition studied

Extracting the mandibular double-sided wisdom teeth

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

The amount of pain

Timepoint

Day of intervention, one day after intervention, two days
 after intervention, three days after intervention

Method of measurement

VAS scale (number)

2

Description

Mouth opening rate

Timepoint

Pre-intervention, 24 hours after intervention, 72 hours
 after intervention

Method of measurement

Millimeters

3

Description

Distance between the corner of the mouth and the
 tragus

Timepoint

Pre-intervention, 24 hours after intervention, 72 hours
 after intervention

Method of measurement

Millimeters

4

Description

The amount of acetaminophen codoine 300 mg taken

Timepoint

Day of intervention, one day after intervention, two days
 after intervention, three days after intervention

Method of measurement

questionnaire

Secondary outcomes

1

Description

age

Timepoint

Before intervention

Method of measurement

questionnaire

2

Description

gender

Timepoint

Before intervention

Method of measurement

questionnaire

3

Description

infection

Timepoint

Before intervention, 24 hours after intervention, 72 hours after intervention

Method of measurement

View, interview

4

Description

Any other anti-inflammatory or analgesic drug

Timepoint

three days after the intervention

Method of measurement

questionnaire

Intervention groups

1

Description

In this double-blind clinical trial, anti-inflammatory and anti-inflammatory effects of topical administration of a 20% tissue bioadhesive made of 100% ginger extract and a mucosal dexamethasone injection of 1.6 mg after extraction of the wisdom teeth will be compared. The similarity of the mandibular teeth is performed by a qualified expert oral and maxillofacial radiologist through panoramic radiography images based on the indications in the radiology images and the classifications available in reference books as well as by a clinical examination by a oral and maxillofacial surgeon. The angle of tooth placement in the jaw, the amount of bone and soft tissue on the tooth, and the tooth position should be similar. Each patient will take amoxicillin 500 mg and metronidazole 400 mg 30 minutes before starting extraction. For each patient, the choice of which treatment is to be done on his right or left tooth will be done using random numbers. Patients will be injected with two carpool of lidocaine anesthetics with inferior alveolar nerve block technique, then removed by the surgeon and under the cut-off procedure of the

mucoperiosteal envelope flap (in case of need for surgery) or by simple tooth extraction. Then, according to a randomized random number, in the cavity of the tooth extracted, the area of 4 cm² of the bioadhesive contains 20% ginger extract will be replaced or 1.8 ml of the dexamethasone dose of 1.6 mg will be injected. The degree of opening the patient's mouth (Trismus status) and the distance between the commissure of oral cavity of the patient and the tragus of his ear (checking the status of swelling) will be measured and recorded before surgery, 24 hours and 72 hours after surgery. A translated VAS pain intensity questionnaire will be provided for patients and they will determine the amount of pain in the respective hours (surgery day and one to three days after surgery). Also, in connection with taking medications, he will be allowed to use acetaminophen codeine 300 mg in case of severe pain. In addition to the numbers of the VAS scale, the number of acetaminophen codin 300 mg tablets taken will be reported to the researcher in each of the days (surgery day and one to three days after surgery). The opening of the mouth and the tragus distance to the corner of his lips, which is considered as a criterion for trismus and swelling of the position, will be measured and recorded by the researcher before surgery 24 hours and 72 hours after surgery. The patient is taking antibiotics amoxicillin 500 and metronidazole 400 every 8 hours and mouthwash (spatula twice a day) up to one week.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Dental Clinic, Faculty of Dentistry, Bushehr University of Medical Sciences

Full name of responsible person

Sahar Zandi

Street address

Shahid Heidari St., Imam Khomeini Avenue, Dental Clinic, Bushehr University of Medical Sciences, Bushehr, Iran.

City

Bushehr

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

The Vice-Chancellor of Research of Bushehr University of Medical Sciences

Full name of responsible person

Dr. Saman Jokar

Street address

Imam Khomeini Street, Bushehr University of Medical Sciences, Faculty of Dentistry

City

Bushehr
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
The Vice-Chancellor of Research of Bushehr 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
School of Dentistry, Bushehr University of Medical Sciences
Full name of responsible person
Sahar Zandi
Position
Student of General Dentistry
Other areas of specialty/work
Street address
Imam Khomeini Street, Bushehr University of Medical Sciences, Faculty of Dentistry
City
Bushehr
Postal code
7514633341
Phone
+98 77 3356 5374
Fax
Email
s.zandi@bpums.ac.irsaharzandi72@yahoo.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Bushehr University of Medical Sciences
Full name of responsible person
Saman jokar
Position

Assistant Professor of Maxillofacial Surgery
Other areas of specialty/work
Street address
Imam Khomeini Street, Bushehr University of Medical Sciences, Faculty of Dentistry
City
Bushehr
Postal code
7514633341
Phone
+98 77 3356 5374
Fax
Email
saman.jokar@yahoo.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
School of Dentistry, Bushehr University of Medical Sciences
Full name of responsible person
Sahar Zandi
Position
Student of General Dentistry
Other areas of specialty/work
Street address
Imam Khomeini Street, Bushehr University of Medical Sciences, Faculty of Dentistry
City
Bushehr
Postal code
Phone
00
Fax
Email
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