Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Jul 2026

Evaluation of the effect of green tea extract on the postoperative pain following surgical removal of the impacted mandibular third molar

Protocol summary

Study aim
Evaluation of the effect of the green tea extract on the postoperative pain following surgical removal of the impacted mandibular third molar

Design
A double-blinded clinical trial with a parallel-group design of 32 self-controlled participants enrolled between June to August 2018.

Settings and conduct
32 participants were selected from June to August 2018 among whom referred to the Dentistry Faulty of Isfahan University of Medical Sciences. surgical extraction of the impacted mandibular third molars was performed in two months. local anesthesia was achieved and an envelope flap was made using a standard incision. after extraction of the tooth, the flap was managed by suturing with silk 3-0. based on the randomized order, saline or green tea-extract-impregnated gauze was applied to the surgical site. patients were given 10 tablets of ibuprofen 400 mg only for using only when the patient is in pain. 6, 12, 24, and 48 hours after surgery, patients were evaluated concerning the postoperative pain using VAS and the number of analgesics. this study was a double-blinded one in which none of the patient and surgeon was not aware of the exact location of the green tea-extract-impregnated gauze.

Participants/Inclusion and exclusion criteria
having bilateral impacted mandibular third molar with the same level of difficulty was considered as the inclusion criteria. any factor affecting the postoperative pain exclude the patient from the study.

Intervention groups
after the extraction of the impacted mandibular third molars in 2 months, based on the randomized order, saline or green tea-exract-impregnated gauze was applied on the surgical site.

Main outcome variables
type of the gauze applied to the surgical site; the score of the VAS for pain in 6, 12, 24, and 48 hours after surgery; the number of analgesics used in 6, 12, 24, and 48 hours after surgery

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20131205015665N4**
Registration date: **2020-07-10, 1399/04/20**
Registration timing: **retrospective**

Last update: **2020-07-10, 1399/04/20**
Update count: **0**

Registration date
2020-07-10, 1399/04/20

Registrant information

Name
Milad Etemadi-Shalamzari

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-05-22, 1397/03/01

Expected recruitment end date
2018-08-22, 1397/05/31

Actual recruitment start date
2018-05-22, 1397/03/01

Actual recruitment end date
2018-08-11, 1397/05/20

Trial completion date
2018-08-13, 1397/05/22

Scientific title
Evaluation of the effect of green tea extract on the postoperative pain following surgical removal of the impacted mandibular third molar

Public title
Evaluation of the effect of green tea extract on the postoperative pain following surgical removal of the impacted mandibular wisdom tooth

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Having bilateral impacted mandibular third molar with the same difficulty based on the spatial direction of the teeth (mesioangular) on preoperative panoramic radiography Having bilateral impacted mandibular third molar with the same difficulty based on the depth of impaction (Pell & Gregory classifications/type B) on preoperative panoramic radiography Having bilateral impacted mandibular third molar with the same difficulty based on the relationship with the anterior border of the ramus (class 1) on preoperative panoramic radiography
Exclusion criteria:
having allergy to green tea products being younger than 18 years old or having more than 30 years of age receiving other drugs like antibiotics, analgesics, and herbal therapy for pain/ infection in the last 30 days presence of any kind of lesion (benign or malignant) in the site of surgery before surgery pregnancy and/or lactation systemic health problems presence or history of pain in the maxillofacial region like temporomandibular joint disorder (TMD) or myofascial pain and dysfunction syndrome (MPDS) before surgery presence of pulpitis drug addiction (methamphetamine, ephedrine, or cocaine)

Age
From **18 years** old to **30 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **32**
More than 1 sample in each individual
Number of samples in each individual: **2**
surgical removal of the impacted mandibular wisdom teeth will be performed with the time interval of two months. based on the patient's ID number and randomization plan, after one surgery green tea-impregnated gauze will be applied on one side and saline-impregnated gauze on the other side.
Actual sample size reached: **31**
More than 1 sample in each individual
Actual sample size in each individual: **2**
surgical removal of the impacted mandibular wisdom teeth was performed with the time interval of two months. based on the patient's ID number and randomization plan, after one surgery green tea-impregnated gauze was applied on one side and saline-impregnated gauze on the other side.

Randomization (investigator's opinion)
Randomized

Randomization description
pseudorandomization will be performed in this study. after considering an identification number from 1 to 32 for each patient; in patients with an odd ID number, green tea-impregnated gauze will be used on the right side and saline-impregnated gauze will be applied to the left side. in patients with an even ID number, green tea-impregnated gauze will be used on the left side and saline-impregnated gauze will be applied to the right side

Blinding (investigator's opinion)
Double blinded

Blinding description
for blinding the participants: they will not be aware of the exact location of application of the green tea-impregnated gauze after surgery for blinding the care provider: the surgeon will not be aware of the exact location of application of the green tea-impregnated gauze after surgery and application of the gauze and patient's instruction will be performed by the researcher and in the absence of the surgeon

Placebo
Used

Assignment
Parallel

Other design features
split-mouth design

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Isfahan university of medical sciences

Street address
oral and maxillofacial surgery department, dentistry faculty, Isfahan university of medical sciences,Hezar-jerib st., Isfahan, Iran.

City
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73461-81746

Approval date
2018-05-15, 1397/02/25

Ethics committee reference number
IR.MUI.REC.1397.3.067

Health conditions studied

1

Description of health condition studied
evaluation of the postoperative pain following application of the green tea-impregnated gauze after surgical extraction of the impacted mandibular third molar
ICD-10 code
G89.18
ICD-10 code description
Other acute postprocedural pain

Primary outcomes

1

Description
severity of the pain based on Visual analogue scale (VAS)
Timepoint
evaluation of the severity of the pain 6, 12, 24, and 48 hours after surgery
Method of measurement
using Visual analogue scale (VAS)

2

Description
number of analgesics (ibuprofen) used after surgery
Timepoint
6, 12, 24,and 48 hours after surgery
Method of measurement
asking the patient

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: All the surgeries will be performed by an experienced surgeon using the same protocol: the povidone-iodine solution will be applied to the surgical site; 2% lidocaine and 1:80,000 epinephrine (Iran, Tehran, Exir) will be used to block the inferior alveolar and long buccal nerves; a mucoperiosteal envelop flap will be created using a standard incision; if needed, bone removal, tooth sectioning, and bone recontouring will be performed with a low-speed hand-piece under sufficient sterile solution irrigation; following tooth removal the socket will be irrigated with 60 ml of saline; the flap will be sutured using 3–0 silk sutures. Green tea extract-impregnated sterile gauze will be used after removing the right or left tooth, according to the randomized order specified before and based on the patient's ID number. Both patients and surgeons will be blinded to the type of gauze. Iranian green tea will be purchased from the market (Iran, Mashhad, Zarghani company). For the preparation of hydroalcoholic extract, green tea will be powdered and 300 grams of the powder will be macerated by 1500 ml of ethanol 70% (v/v) for 72 hours. The extract will be then shaken, filtered and the solvent will be removed in a vacuum evaporator to obtain a semi-solid extract, and then it will be placed in an oven at 60°C for 72 hours. Patients will be instructed to take no painkiller or narcotics 12 hours before the procedure. As the surgery finished they will be given 10 Advalgine (Ibuprofen Lysine 400 mg) tablets and told to use them as the only medication for pain relief. They also will be instructed not to drink green tea beverages 48 hours after the operation. Respectively 6, 12, 24, and 48 hours after the end of the procedure by telephone contact, they will be asked about the presence and intensity of pain on the surgical site. On the third day after the operation, patients will be examined by the surgeon to note if they had experienced a dry socket. The decrease in the VAS pain scores as well as the number of analgesics used will be calculated for each patient.
Category
Treatment - Other

2

Description
Intervention group 2: All the surgeries will be performed by an experienced surgeon using the same protocol: the povidone-iodine solution will be applied to the surgical site; 2% lidocaine and 1:80,000 epinephrine (Iran, Tehran, Exir) will be used to block the inferior alveolar and long buccal nerves; a mucoperiosteal envelop flap will be created using a standard incision; if needed, bone removal, tooth sectioning, and bone recontouring will be performed with a low-speed hand-piece under sufficient sterile solution irrigation; following tooth removal the socket will be irrigated with 60 ml of saline; the flap will be sutured using 3–0 silk sutures. Green tea extract-impregnated sterile gauze will be used after removing the right or left tooth, according to the randomized order specified before and based on the patient's ID number. Both patients and surgeons will be blinded to the type of gauze. Patients will be instructed to take no painkiller or narcotics 12 hours before the procedure. As the surgery finished they will be given 10 Advalgine (Ibuprofen Lysine 400 mg) tablets and told to use them as the only medication for pain relief. They also will be instructed not to drink green tea beverages 48 hours after the operation. Respectively 6, 12, 24, and 48 hours after the end of the procedure by telephone contact, they will be asked about the presence and intensity of pain on the surgical site. On the third day after the operation, patients will be examined by the surgeon to note if they had experienced a dry socket. The decrease in the VAS pain scores as well as the number of analgesics used will be calculated for each patient.
Category
Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Isfahan University of Medical Sciences, Dentistry Faculty

Full name of responsible person
Milad Etemadi Shalamzari

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Oral and Maxillofacial surgery section, Dentistry Faculty, Isfahan University of medical Sciences, Hezar-jerib street, Isfahan, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
Shaghayegh Haghjooy Javanmard

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Grant name

Grant code / Reference number
397067

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

Title of funding source
Esfahan 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
Esfahan University of Medical Sciences

Full name of responsible person
Milad Etemadi Shalamzari

Position
Assistant professor

Latest degree
Specialist

Other areas of specialty/work
Dentistry

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Latest degree
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
there is no further information

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

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
study protocol

When the data will become available and for how long
starting 6 months after publication

To whom data/document is available
available for whom working in academic institutions

Under which criteria data/document could be used
no other condition

From where data/document is obtainable
sending request email to "gtajmiri.gt@gmail.com"

What processes are involved for a request to access data/document
10 days after the request, data will be accessible

Comments