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Myrrh mouthwash use after teeth extraction

Submission date
16/04/2019

Recruitment status
No longer recruiting

Registration date
19/04/2019

Overall study status
Completed

Last Edited
22/01/2021

Condition category
Oral Health

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
The early period after tooth extraction is a critical period for wound healing. Wounds usually heal normally unless interfered with factors either local or systemic. In certain circumstances the early wound healing can be improved by interventions such as antibiotics, mouthwashes, or topical medicine applications. The aim of this study is to investigate the effect of myrrh mouthwash on wound healing during the early period after tooth extraction.

Who can participate?
Physically healthy adult patients referred for simple tooth extraction

What does the study involve?
Participants are assessed and their tooth is extracted under local anaesthetic in the standard manner. They then receive a medication to be used twice a day starting from the second day after surgery. Selection of the material to be used as a mouthwash is by chance. Participants in one group are given the test medication mouthwash while participants of the other group are given a placebo (dummy) mouthwash. The medication is given in a plastic pack to take home, dispense its contents in a cup of warm water, and rinse their mouth thoroughly with half of the cup in the morning and another half at bedtime. Participants do this daily until the seventh day after surgery. Participants are seen in the clinic for follow up on the seventh day. During the follow up the wound healing process is assessed and oral x-rays may be taken according to the clinical need. The examination follow up appointment takes 20 minutes using routine examination instruments.

What are the possible benefits and risks of participating?
Participants may have better wound healing if they are using the mouthwash. However, this can’ t be guaranteed. Others may benefit in the future from the results of this study. There are no known risks of using the mouthwash.

Where is the study run from?
King Saud University, Riyadh, KSA

When is the study starting and how long is it expected to run for?
November 2017 to March 2019

Who is funding the study?
Funded by the researcher

Who is the main contact?
Dr Raniah Al Eid
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Contact information

Type(s)
Scientific

Contact name
Dr Raniah Al Eid

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
E-17-2609

Study information

Scientific Title
Efficacy of Commiphora myrrh mouthwash on the early wound healing after tooth extraction: a randomized controlled trial

Study objectives
To prove the healing potentiation effect of myrrh mouthwash during the early post extraction period.

Ethics approval required

Old ethics approval format

Ethics approval(s)
Approved 30/11/2017, Institutional Review Board (IRB) in King Saud University (College of Medicine, KSU; Tel.: (1) 469 1531, (1) 469 1532; Email: balferez@ksu.edu.sa; irb.medksu@hotmail.com), ref: E-17-2609

Study design
Randomized double-blind placebo control based study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet
Not available in web format, contact details: +966 (0)500850350

Health condition(s) or problem(s) studied
Tooth extraction

Interventions
40 healthy adult patients were included in the study. Estimating sample size for a randomized controlled trial (using EPI Info 7, StatCalc, CDC, USA), assuming 95% confidence level and statistical power of 90%, the sample size was estimated as 36 patients (18 cases + 18 controls). After allowing 10% overestimation for any loss due to following up, the final sample size was calculated as 40 patients (20 cases + 20 controls).

The procedure was performed in a randomized double-blind placebo control based study in which both the participants and the examiner were masked. Subjects were assigned at random to the exposure and the control and only the dental assistant knows them. All participants underwent dental extraction under local anaesthesia at Oral and Maxillofacial Surgery Clinic, College of Dentistry, King Saud University. Standard pre-operative and post-operative extraction protocols adhered. All patients were advised to have good oral hygiene postoperatively.

Patients were randomized into two groups:

Group A (test group) were prescribed to use Commiphora molmol (myrrh) extract as a mouthwash twice daily for 7 days beginning from the 1st postoperative day. The myrrh was prepared by the researcher in a form of mouthwash of a 1:5 @ 90% of myrrh . The researcher provided the myrrh commercially, then it was ground and packed in unlabelled white filter paper packs. Patients were instructed to put each pack in a cup of warm water for use as a mouthwash.

Group B (control group) were prescribed to use saline mouthwash twice daily for 7 days beginning from the 1st postoperative day. The saline was prepared by the researcher in which each pack contains 9 grams of sodium chloride (NaCl). Similarly, patients were instructed to put each pack in a cup of warm water for use as a mouthwash. All packs used for both groups were the same: white filter paper.

Randomization of the patients was double-blinded to the clinician and the participant and was documented only by a neutral dental assistant. In order to eliminate bias each one of the mouthwash pack was labelled with a code number according to the randomization sequence.

The post-operative assessment was performed on the 7th day. It included a recording of patients' symptoms, systemic and local findings. The local findings included the presence /absence of swelling or facial asymmetry, examination of the oral condition including colour of the gingiva around the extracted socket, presence of any signs of infection as pain, tenderness, abnormal odour, pus discharge, bleeding, socket size, loss of function such as limited mouth opening or numbness and any other findings.

Intervention Type
Other

Primary outcome measure
Patients' symptoms, systemic and local findings. The local findings included the presence /absence of swelling or facial asymmetry, examination of the oral condition including colour of the gingiva around the extracted socket, presence of any signs of infection such as pain (measured using Visual Analogue Scale), tenderness, abnormal odour, pus discharge, bleeding, socket size, loss of function such as limited mouth opening (using a calibrated digital caliper) or numbness, and any other findings. A single examiner performed all clinical measurements prior to surgery (baseline) as well as on the 7th day in the postoperative period.

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
30/11/2017

Completion date
16/03/2019

Eligibility

Key inclusion criteria
1, Young adults in the age range of 18-45 years old ASA I adults
2. The tooth that is indicated for extraction is not infected
3. Absence of any pathology in the area of the tooth for extraction and neighbouring teeth
4. Teeth that require simple extraction
5. The patient should accept to participate in the study and sign a consent emphasizing his/her understanding of all possible risks, the aim and methodology of the study

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
45 Years

Sex
Both

Target number of participants
40 participants

Total final enrolment
40

Key exclusion criteria
1. Medically compromised patients
2. Pregnant females
3. Teeth that require surgical extractions
4. Teeth related to abscess or pathology

Date of first enrolment
16/09/2018

Date of final enrolment
16/03/2019

Locations

Countries of recruitment
Saudi Arabia

Study participating centre
King Saud University College of dentistry
Riyadh
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11314

Sponsor information

Organisation

King Saud University College of Medicine and King Khalid University Hospital

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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/046gga527

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Planned publication in International Dental Journal as soon as possible immediately following trial registration.

Intention to publish date
18/07/2019

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Raniah Al Eid (dr.raniahaleid@hotmail.com). Patient's confidentiality is maintained and data doesn't include any personal information nor pictures. The data included results of clinical assessment and referred to by codes instead of names. The data is analyzed statistically using SPSS, descriptive statistics and Mann-Whitney Wilcoxon test. All participants have signed the informed consent after understanding the study and agreed to participate. The data can be submitted for the reviewers if requested for the sake of scientific review and not for publication.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/01/2021	22/01/2021	Yes	No