Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparison of bacterial contamination and complications after impacted wisdom tooth surgery using sterile gloves and clean gloves

Protocol summary

Study aim
Comparison of bacterial contamination and complications after impacted wisdom tooth surgery with sterile and clean gloves

Design
Clinical trial, randomized, parallel group trial with single blinded outcome assesment

Settings and conduct
This study will be performed on patients referred for wisdom tooth surgery in the mandible to the clinic of the School of Dentistry and the private office of the maxillofacial surgeon in Bojnourd. The study will be performed as single blind and the patient is unaware. Samples are taken from all surfaces of gloves before and after surgery to compare bacterial contamination with sterile swabs. Also, immediately after the extraction of the tooth,swab is immersed in sockrt and the samples taken are transferred to the laboratory. One week later, the patient is referred again and evaluated for complications and recorded in the checklist.

Participants/Inclusion and exclusion criteria
People aged 18-35 who needed widsom tooth surgery compeletly hidden in mandible All patients are non-smokers and non-alcoholis.All patient should be in ASA1 group.Patient without systemic disease and immunodeficiency Patients who are taking antibiotics for the current infection or need antibiotic prophylaxis before surgery.Patients who surgery lasts more than 30 minutes.Patient with uncpontrolled diabetes or bleeding disorders.Paatients receiving steroid therapy.Patients with a history of head and neck radiotherapy.Existence of deep caries and pericronitis. .

Intervention groups
The 40 patients who were included in the study were randomly divided into two groups, one using sterile gloves and the other using clean gloves for the surgeon and his assistant.

Main outcome variables
Acute socket inflammation; Acute socket infection; Dry socket; Fever ;Pain;Colony forming unit

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210508051216N1**
Registration date: **2021-05-31, 1400/03/10**
Registration timing: **registered_while_recruiting**

Last update: **2021-05-31, 1400/03/10**
Update count: **0**

Registration date
2021-05-31, 1400/03/10

Registrant information

Name
Sabah Oghazian

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 58 3223 8934

Email address
s.oghazian@nkums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-05-29, 1400/03/08

Expected recruitment end date
2021-09-20, 1400/06/29

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Comparison of bacterial contamination and complications after impacted wisdom tooth surgery using sterile gloves and clean gloves

Public title
Comparison of complications of wisdom teeth with surgical and clean gloves

Purpose
Health service research

Inclusion/Exclusion criteria

Inclusion criteria:
People aged 18-35 who needed widsom tooth surgery compeletly hidden in mandible All patients are non-smokers and non-alcoholis All patient should be in ASA1 group. Patient without systemic disease and immunodeficiency

Exclusion criteria:
Patients who are taking antibiotics for the current infection or need antibiotic prophylaxis before surgery. Patients who surgery lasts more than 30 minutes. Patient with uncpontrolled diabetes or bleeding disorders. Paatients receiving steroid therapy. Patients with a history of head and neck radiotherapy. Existence of deep caries and the need for root canal thrapy in other teeth and other inflammatory problems such as pericronitis.

Age
From **18 years** old to **35 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
Using limited randomization and the method of random allocation law due to the tendency to choose equal sample size in two groups; the researcher involved based on the sample size of 40 in this study: in the randomization process, 20 sheets with A and 20 The sheet with the number B written on it will be placed in a lottery container and then the papers will be randomly removed from the lottery container and a random sequence will be recorded. To ensure concealment, the names of the selected groups in the envelopes They will be coded according to a random sequence (the researcher will make sure that the envelopes are sealed and similar in appearance) and to ensure compliance with the allocation process to prevent or reduce possible bias, the person involved in creating a random program It will be a separate project from other researchers.

Blinding (investigator's opinion)
Single blinded

Blinding description
Due to the subjectivity of some of the measured complications (pain) of the study, we do it as single blind so that only at the beginning of the study and informed consent to the patient will be told the procedure and whether he is in the group of sterile or non-sterile gloves The patient will remain unaware

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

1

Registry name

Secondary trial Id

Registration date
empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of North khorasan University of Medical Sciences

Street address
N17, Zafar Ave, Baharan Ave, Faramarz Abbasi Blvd

City
Mashhad

Province
Razavi Khorasan

Postal code
9197855711

Approval date
2021-05-01, 1400/02/11

Ethics committee reference number
IR.NKUMS.REC.1400.008

Health conditions studied

1

Description of health condition studied
Wisdom tooth surgery completely hidden in mandible with sterile and clean glove

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Fever

Timepoint
One week after lower wisdom tooth surgery

Method of measurement
One week after surgery, all complications such as fever

above 37.5 ° C with a thermometer.

2

Description
Pain with a score of 0-10 by the patient
Timepoint
One week after lower wisdom tooth surgery
Method of measurement
Postoperative pain with a score of 0-10 by the patient

3

Description
Dry socket
Timepoint
One week after lower wisdom tooth surgery
Method of measurement
Persistent throbbing pain

4

Description
Acute socket inflammation
Timepoint
One week after lower wisdom tooth surgery
Method of measurement
Acute socket inflammation without pus and systemic fever

5

Description
Acute socket infection,
Timepoint
One week after lower wisdom tooth surgery
Method of measurement
Acute socket infection is associated with pus and systemic fever

6

Description
Colony- forming unit
Timepoint
One week after lower wisdom tooth surgery
Method of measurement
The number of colony units is calculated by counting the number of colonies formed on the culture medium

Secondary outcomes

1

Description
Swelling
Timepoint
One week after surgery
Method of measurement
Swelling of the gums at the surgical site, which may appear asymmetrically on the face.

2

Description
Pus and redness in gingiva
Timepoint
One week after surgery
Method of measurement
Removal of pus from the surgical site and redness of the gums, which can be seen one week after surgery.

Intervention groups

1

Description
Intervention group: Use of sterile maxter gloves made in Malaysia for mandibular impact wisdom tooth surgery
Category
Other

2

Description
Intervention group: Using op-perfect clean gloves made in Iran for mandibular impact wisdom tooth surgery
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
North Khorasan School of Dentistry
Full name of responsible person
Oghazian Sabah
Street address
Bojnourd, Arkan Road, next to Imam Hassan Hospital
City
Bojnourd
Province
North Khorasan
Postal code
9417694735
Phone
+98 58 3229 6764
Email
m.anbarestani1374@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Bojnourd University of Medical Sciences
Full name of responsible person
Amani Amir
Street address
Bojnourd - Shahriar St. - Above Imam Ali Hospital - Faculty of Medicine - Vice Chancellor for Research

and Technology

City
Bojnourd

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North Khorasan

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9417694780

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Email
A.Amani@nkums.ac.ir

Grant name

Grant code / Reference number

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

Title of funding source
Bojnourd 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
Bojnourd University of Medical Sciences

Full name of responsible person
Oghazian Sabah

Position
Associate professor

Latest degree
Specialist

Other areas of specialty/work
Dentistry

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Arkan Road, next to Imam Hassan Hospital, School of Dentistry

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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

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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
This study is for thesis.

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

Not applicable