

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jun 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 uncontrolled 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 wisdom tooth surgery completely hidden in mandible. All patients are non-smokers and non-alcoholics. All patients 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 whose surgery lasts more than 30 minutes. Patients with uncontrolled diabetes or bleeding disorders. Patients receiving steroid therapy. Patients with a history of head and neck radiotherapy. Existence of deep caries and the need for root canal therapy in other teeth and other inflammatory problems such as pericoronitis.

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

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North Khorasan

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9417694735

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+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

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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

Street address

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

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Position

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Person responsible for updating data

Contact

Name of organization / entity

Bojnourd University of Medical Sciences

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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