Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparison of standard incision and comma shaped incision for impacted mandibular third molar surgery

Protocol summary

Study aim
Aim of the study is to use comma shaped incision for impacted mandibular third molars rather than traditional ward incision because comma incision is expected to be associated with lesser incidence of postoperative pain, swelling and trismus.

Design
A concealed, randomized, blinded controlled clinical trial with a parallel group design of 100 patients, enrolled between 3rd October 2018 to 2nd April 2019 ,and followed for 6 months

Settings and conduct
Non-probability, Consecutive sampling done in dept of Oral and Maxillofacial Surgery, AFID Rawalpindi.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: Patients with fully impacted lower third molars; Patients having physical status 1 according to ASA classification. Exclusion Criteria: Pregnant women, nursing mothers; Patients with non-localized odontogenic infection; Tooth associated with pathologies, Patients on radiotherapy, chemotherapy, bisphosphonates, bone diseases

Intervention groups
Intervention group 1: Surgical removal of impacted mandibular third molar using comma-shaped incision.
Intervention group 2: Surgical removal of impacted mandibular third molar using traditional ward incision.

Main outcome variables
Pain; swelling; trismus.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230714058773N2**
Registration date: **2023-09-03, 1402/06/12**
Registration timing: **retrospective**
Last update: **2023-09-03, 1402/06/12**
Update count: **0**

Registration date
2023-09-03, 1402/06/12

Registrant information

Name
Tehmina Maryam

Name of organization / entity
Armed forces institute of dentistry, combined military hospital, Rawalpindi, Pakistan

Country
Pakistan

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+92 333 9576737

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-10-03, 1397/07/11

Expected recruitment end date
2019-04-02, 1398/01/13

Actual recruitment start date
2018-10-03, 1397/07/11

Actual recruitment end date
2019-04-02, 1398/01/13

Trial completion date
2019-04-04, 1398/01/15

Scientific title
Comparison of standard incision and comma shaped incision for impacted mandibular third molar surgery

Public title
Comparison of standard incision and comma shaped incision for impacted mandibular third molar surgery

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with fully impacted lower third molars (more than two-thirds of the crown covered with alveolar bone evaluated on periapical radiograph or OPG) Patients having physical status 1 according to American Society of Anesthesiologists (ASA) classification.

Exclusion criteria:

Pregnant women, nursing mothers Patient with non-localized odontogenic infection Tooth associated with pathologies i.e. cysts, mandibular angle fractures, tumors Patients on radiotherapy, chemotherapy, bisphosphonates, bone diseases e.g. Paget's disease.

Age

From **18 years** old to **45 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **100**

Actual sample size reached: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Non-probability, Consecutive sampling was done in startified randomization by allotment of random numbers.Randomization was done by giving Odd numbers to the intervention group and even numbers to the control group

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of armed forces institute of dentistry CMH Rawalpindi

Street address

Range road Rawalpindi

City

Rawalpindi

Postal code

46000

Approval date

2018-10-03, 1397/07/11

Ethics committee reference number

905/Trg-ABP1K2

Health conditions studied

1

Description of health condition studied

Third molar impacted and embedded teeth

ICD-10 code

K01

ICD-10 code description

Embedded and impacted teeth

2

Description of health condition studied

Third molar embedded teeth

ICD-10 code

K01.1

ICD-10 code description

Impacted teeth

Primary outcomes

1

Description

Pain

Timepoint

0 and 1st post operative day

Method of measurement

10 point Visual Analog Scale as None, Weak, Moderate and Severe pain . If VAS ≥ 7 then it was considered pain

2

Description

Post Operative swelling

Timepoint

1st and 3rd post operative day

Method of measurement

Swelling assessed as distance measured between: Lateral canthus of the eye to the gonion angle; Tragus to the commissure of the mouth; Tragus to pogonion. These readings were taken pre-operatively and compared with the readings taken on 1st and 3rd day post-operatively.

3

Description

Trismus/ mouth opening

Timepoint

0 and 1st post operative day

Method of measurement

Mouth opening measured after 24 hours of surgery as interincisal distance in millimeters and patient had trismus if interincisal mouth opening is less than or equal to 29 mm

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: A total of 50 cases with fully impacted lower third molars of age 18-45 years and both genders were included. Pregnant women, nursing mothers, patient with non-localized odontogenic infection, tooth associated with pathologies i.e. cysts, mandibular angle fractures, tumors, patients on radiotherapy, chemotherapy, bisphosphonates, bone diseases e.g. Paget's disease were excluded. Surgical removal of impacted mandibular third molar was done under local anaesthesia using comma shaped incisions. Postoperative pain experienced by patient after third molar surgery was assessed at 24 hours after extraction on 10 point Visual Analog Scale as None, Weak, Moderate and Severe pain. If VAS ≥ 7 then it was considered pain. Mouth opening was measured after 24 hours of surgery as interincisal distance in millimeters and patient had trismus if interincisal mouth opening is less than or equal to 29 mm. Swelling was assessed as distance measured between: Lateral canthus of the eye to the gonion angle; Tragus to the commissure of the mouth; Tragus to pogonion.

Category
Treatment - Surgery

2

Description
Control group: 50 cases with fully impacted lower third molars of age 18-45 years and both genders were included. Pregnant women, nursing mothers, patient with non-localized odontogenic infection, tooth associated with pathologies i.e. cysts, mandibular angle fractures, tumors, patients on radiotherapy, chemotherapy, bisphosphonates, bone diseases e.g. Paget's disease were excluded. Surgical removal of impacted mandibular third molar was done under local anaesthesia using standard ward flap incision Postoperative pain experienced by patient after third molar surgery was assessed at 24 hours after extraction on 10 point Visual Analog Scale as None, Weak, Moderate and Severe pain. If VAS ≥ 7 then it was considered pain. Mouth opening was measured after 24 hours of surgery as interincisal distance in millimeters and patient had trismus if interincisal mouth opening is less than or equal to 29 mm. Swelling was assessed as distance measured between: Lateral canthus of the eye to the gonion angle; Tragus to the commissure of the mouth; Tragus to pogonion.

Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Armed forces institute of dentistry CMH ,Rawalpindi ,Pakistan
Full name of responsible person
Tehmina Maryam
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
Nazir Khan
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Armed forces institute of dentistry CMH Rawalpindi
Proportion provided by this source
50
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

2

Sponsor
Name of organization / entity
Armed forces institute of dentistry CMH Rawalpindi
Full name of responsible person
Noman Tahir
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Grant name

Grant code / Reference number

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

Title of funding source
Armed forces institute of dentistry CMH Rawalpindi

Proportion provided by this source
50

Public or private sector
Private

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
Armed forces institute of dentistry CMH Rawalpindi
Full name of responsible person
Tehmina Maryam
Position
Registrar
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Other areas of specialty/work
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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
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
Not applicable

Data Dictionary
No - There is not a plan to make this available