Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 Jul 2026

Comparison of Intrasocket Application of Hyaluronic Acid+Gelfoam Vs Gelfoam Alone to Reduce Post-Operative Pain and Trismus after Surgical Extraction of Lower Wisdom Teeth

Protocol summary

Study aim
Compare the effectiveness of intra-socket application of HA+gelfoam vs gelfoam (placebo) alone to reduce the post-op pain and trismus.

Design
Prospective, Split-mouth, Double-blinded Randomized controlled trial. Intervention group Hyaluronic Acid+Gelfoam, Control group-Gel-foam alone. Single center study.

Settings and conduct
After taking ethical approval, 15 patients matching the inclusion criteria will be selected from the Out patient department of Oral and Maxillofacial surgery, CMH Medical College & Institute of Dentistry, Lahore. Surgical extraction will be performed by a single surgeon (researcher herself) under local anesthesia (LA). Decided Material will be placed into the socket and closure with silk sutures will be done. The patient will be prescribed antibiotics and analgesics. Post-operatively pain and trismus will be evaluated on the 1st, 2nd and 7th day by using Numerical rating scale (NRS) and ruler measuring Inter-incisal distance in millimeters. Score will be documented by co-researcher to eliminate bias.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: 18-40 years of age Non-smoker, non-alcoholic, similar difficulty level on both sides according to Pederson scale Exclusion Criteria: systolic blood pressure (>140 mmHg,< 90 mmHg), diastolic (>90mmHg , <60mmHg) Any history of allergy or adverse effects to antibiotics, analgesics, or local anesthetics. Acute infection Any physical or mental disability. Pregnant woman and any use of contraceptives or corticosteroids Any patient taking antibiotics and analgesics for 15 days before operation Taken antidepressants 5 days before the surgery

Intervention groups
Group that receives Intrasocket Hyaluronic Acid+ Gelfoam

Main outcome variables
Pain and Trismus after Surgical Extraction of Lower Wisdom Teeth on 1st 2nd and 7th post operative day

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20240301061136N1**
Registration date: **2024-03-28, 1403/01/09**
Registration timing: **prospective**

Last update: **2024-03-28, 1403/01/09**
Update count: **0**

Registration date
2024-03-28, 1403/01/09

Registrant information

Name
Rida Binte Zahid

Name of organization / entity
CMH Lahore Medical College and Institute of Dentistry Lahore

Country
Pakistan

Phone
+92 42 35929717

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-09-01, 1403/06/11

Expected recruitment end date

2025-03-01, 1403/12/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Intrasocket Application of Hyaluronic Acid+Gelfoam Vs Gelfoam Alone to Reduce Post-Operative Pain and Trismus after Surgical Extraction of Lower Wisdom Teeth

Public title

Effect of Intrasocket Application of Hyaluronic Acid

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

18-40 years of age Do not have any systemic disease Non-smoker, Non-alcoholic symmetrically impacted third molars on both sides of the mandible Require surgical extraction of impacted teeth Similar difficulty level on both sides according to Pederson scale Gave consent for participation

Exclusion criteria:

systolic blood pressure (>140 mmHg,< 90 mmHg), diastolic (>90mmHg , <60mmHg). Any history of allergy or adverse effects to antibiotics, analgesics, or local anesthetics Acute infection such as pericoronitis and/or complication or pain on the impaction area before extraction Any physical or mental disability Pregnant woman and any use of contraceptives or corticosteroids which can affect the postsurgical complication of healing and amount of swelling on the face Tobacco use in any form Any patient taking antibiotics and analgesics for 15 days before operation Taken antidepressants 5 days before the surgery Non-cooperative patient

Age

From **18 years** old to **40 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **15**

More than 1 sample in each individual

Number of samples in each individual: **2**

Both sides requiring extraction. On one side Hyaluronic Acid with Gel-foam will be placed and on the other side only Gel-foam will be placed.

Randomization (investigator's opinion)

Randomized

Randomization description

Two lists of integers will be generated via www.random.org representing the two groups (Hyaluronic Acid + gel-foam vs Gel-foam alone). Each side of the patient's mouth will be allotted a sample number. The integers will then be looked up in the list generated to decide which material has to be placed.

Blinding (investigator's opinion)

Double blinded

Blinding description

The patient will not know which material is placed on which side of the mouth. Post-operatively, pain will be evaluated on the 1st, 2nd and 7th day by using Numerical rating scale (NRS) and trimus will be evaluated through Inter-incisal distance. Score will be documented by co-researcher to eliminate bias.

Placebo

Used

Assignment

Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Office of Research, Innovation & Commercialization (L-ORIC) CMH Lahore Medical College & Institute o

Street address

G9QC+GGM CMH Lahore Medical College, Abdul Rehman Rd, Sarwar Colony, Lahore, Punjab

City

Lahore

Postal code

54000

Approval date

2023-12-08, 1402/09/17

Ethics committee reference number

ORIC-CMH-LMC-2023-0097

Health conditions studied

1

Description of health condition studied

Post operative pain and trismus (mouth opening)

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Pain and trismus

Timepoint

1st 2nd and 7th post operative day

Method of measurement

Pain measured through NRS and Trismus is the Inter-incisal distance measured in mm using a ruler

Secondary outcomes

1

Description
Dry socket and painkiller use
Timepoint
3rd 4th and 7th post operative day
Method of measurement
Visual assessment of dry socket symptoms. Painkiller use measured by the number of tablets used post operatively

Intervention groups

1

Description
Intervention group: this is the site of surgical extraction which will receive Hyaluronic acid+ Gelfoam within the socket. 1.7ml of 20mg/2ml Hyaluronic Acid will be used (Hylagun prefilled injections) along with Gelfoam (haemostatic gelatin sponge) as a scaffold. After surgical extraction Gelfoam will be impregnated with Hyaluronic Acid which will then be placed within the extraction socket and closure will be done with silk 3.0 sutures.
Category
Treatment - Other

2

Description
Control group: this is the site of surgical extraction which will receive Gelfoam (haemostatic gelatin sponge) alone. This is used as placebo to compare the effect of our intervention. After the delivery of the tooth. The socket will be filled with Gelfoam and closure will be done with silk 3.0 sutures.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
CMH LAHORE MEDICAL COLLEGE AND INSTITUTE OF DENTISTRY LAHORE
Full name of responsible person
Dr. Rida Binte Zahid
Street address
G9QC+GGM CMH Lahore Medical College, Abdul Rehman Rd, Sarwar Colony, Lahore, Punjab
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https://cmhlahore.edu.pk/

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
CMH Lahore Medical College and Institute of Dentistry
Full name of responsible person
Dr. Rida Binte Zahid
Street address
G9QC+GGM CMH Lahore Medical College, Abdul Rehman Rd, Sarwar Colony, Lahore, Punjab
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Phone
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Email
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Web page address
https://cmhlahore.edu.pk/
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
CMH Lahore Medical College and Institute of Dentistry
Proportion provided by this source
100
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
CMH Lahore Medical College and Institute of Dentistry
Full name of responsible person
Dr. Rida Binte Zahid
Position
Post graduate trainee
Latest degree
Bachelor
Other areas of specialty/work
Dentistry
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Person responsible for scientific inquiries

Contact

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Full name of responsible person
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Person responsible for updating data

Contact

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Full name of responsible person
Dr. Rida Binte Zahid

Position
Post graduate trainee

Latest degree
Bachelor

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

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

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

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

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

Title and more details about the data/document
All the collected IPD

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

To whom data/document is available
People working in academic institutes

Under which criteria data/document could be used
By mailing a request. Data can be used to help them establish there study protocol

From where data/document is obtainable
Email ID

What processes are involved for a request to access data/document
Provide official information on an institutional letter head along with a mail.

Comments