ISRCTN11664472 https://doi.org/10.1186/ISRCTN11664472

Application of thermosensitive hydroxybutyl chitosan hydrogel after third molar extraction

Submission date
23/10/2023

Recruitment status
No longer recruiting

Registration date
27/10/2023

Overall study status
Completed

Last Edited
29/04/2024

Condition category
Oral Health

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

Plain English summary of protocol

Background and study aims
Impacted third molars are teeth at the back of the mouth that don't have enough room to emerge or develop normally. The extraction of impacted third molars is one of the most common operations in oral and maxillofacial surgery, and composite wound dressings with hydroxybutyl chitosan as the core have great prospects for application. The aim of this study is to assess the effect of a thermosensitive hydroxybutyl chitosan hydrogel on the postoperative reaction and quality of life of patients treated with impacted mandibular third molar extraction.

Who can participate
Patients aged 18-35 years undergoing impacted mandibular (lower jaw) third molar extraction

What does the study involve?
Participants underwent impacted mandibular (lower jaw) third molar extraction and were randomly allocated to one of two groups. A thermosensitive hydroxybutyl chitosan hydrogel was used in the study group, and normal saline stored at the same temperature was used in the control group. Pain, facial swelling and mouth opening were evaluated on the first, third and seventh days after the operation. Quality of life and wound healing scores were evaluated on the third and seventh days after the operation.

What are the possible benefits and risks of participating?
There is almost no risk in this study and patients can withdraw at any time if they feel unwell during the study. The main risk is the risk of extraction of mandibular third molars, such as lower alveolar nerve injury and wound infection.

Where is the study run from?
First Affiliated Hospital of Anhui Medical University (China)

When is the study starting and how long is it expected to run for
June 2022 to June 2023

Who is funding the study
First Affiliated Hospital of Anhui Medical University (China)

Who is the main contact?
Min-gen Yang, 635550525@qq.com

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Effect of thermosensitive hydroxybutyl chitosan hydrogel on postoperative reaction and quality of life after impacted mandibular third molar extraction: a split-mouth, randomized, double-blind, clinical trial

Study objectives
The original hypothesis was that there was no significant difference in the postoperative response or quality of life of patients after impacted mandibular third molar extraction treated with and without thermosensitive hydroxybutyl chitosan (ts-HBC) hydrogel.

Ethics approval required
Ethics approval required

Ethics approval(s)

approved 26/07/2023, First Affiliated Hospital of Anhui Medical University Committee On Medical Ethics (No.218 Jixi Road, Shushan District, Hefei City, 230000, China; +86 (0)551 6292 2017; 180003052@qq.com), ref: Quick-PJ 2023-09-50

Study design
Single-center double-blind randomized controlled trial

Primary study design
Interventional

Study type(s)
Quality of life, Treatment, Efficacy

Health condition(s) or problem(s) studied
Impacted mandibular third molar extraction

Interventions
Participants were divided into experimental and control groups, the control group was given saline stored at the same temperature and the experimental group was given hydrogel.

Randomization procedure:
The two groups were preoperatively prepared using four sealed opaque envelopes; one pair to determine whether to use the hydrogel, and the other pair to determine whether to use the hydrogel on the left or right side. Before the operation, the patients were asked to extract an envelope from each of the two pairs, and the experimental group and the control group were determined according to the combined results.

Intervention Type
Procedure/Surgery

Primary outcome(s)
1. Pain measured using the visual analogue scale (VAS) score on the first, third and seventh days after the operation
2. Swelling: distance from the outer canthus to the mandibular angle (I), the tragus to the mouth angle (II) and the tragus to the mandibular angle (III) measured using a tape measure, and the following formula was applied: (I + II + III)/3 (mm) at baseline and the first, third and seventh days after the operation
3. Mouth opening: distance between the tips of the upper and lower central incisors was measured using a Vernier calliper to evaluate the degree of mouth opening at baseline and the first, third and seventh days after the operation

Key secondary outcome(s))
1. Quality of life measured using a questionnaire which included questions on social isolation, diet, sleep, appearance, and speech on the third and seventh days after the operation
2. Wound healing: the index reported was used to evaluate wound healing. The total score was 5 points, with higher scores indicating better healing, on the third and seventh days after the operation.

Completion date
07/06/2023

Eligibility

Key inclusion criteria
1. Age 18-35 years
2. American Society of Anaesthesiologists (ASA) status 1-2
3. No seafood allergies
4. Pell, Gregory and Winter classification of class I, position B, and horizontal impaction, respectively
5. Good oral hygiene
6. No systemic diseases
7. Ability to cooperate in completing postoperative follow-up

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
35 years

Sex
All

Total final enrolment
60

Key exclusion criteria
1. Contraindications to tooth extraction
2. Seafood allergy
3. Failure to follow the research protocol after the operation
4. Time difference between the two operations of more than 10 min
5. Periodontal disease or acute wisdom tooth pericoronitis with antibiotic use in the past week
6. Allergy to drugs used in the research process
7. Incomplete postoperative follow-up

Date of first enrolment
01/06/2022

Date of final enrolment
31/05/2023

Locations

Countries of recruitment
China

Study participating centre
The First Affiliated Hospital of Anhui Medical University
No.218 Jixi Road, Shushan District
Hefei City
China
230000

Sponsor information

Organisation
First Affiliated Hospital of Anhui Medical University

ROR
https://ror.org/03t1yn780

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
First Affiliated Hospital of Anhui Medical University

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Min-gen Yang (635550525@qq.com).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results			29/04/2024	No	No