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The effectiveness and safety of oral adhesive bandage for extraction wound management

Submission date	Recruitment status	[ ] Prospectively registered
29/10/2023	No longer recruiting	[ ] Protocol
Registration date	Overall study status	[ ] Statistical analysis plan
20/11/2023	Completed	[ ] Results
Last Edited	Condition category	[ ] Individual participant data
13/11/2023	Oral Health	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
This study compares oral adhesive bandages with the classic compression method to evaluate this wound dressing material in improving postoperative comfort, wound healing and hemostasis (stopping bleeding) in tooth extraction.

Who can participate?
Adult patients requiring surgical removal of one single tooth

What does the study involve?
In this study, subjects are randomly assigned to one of two groups (a randomized controlled clinical trial): an experimental group receiving the intervention that is being tested, the oral adhesive bandages used as wound dressing, and the other (the comparison group or control) receiving an alternative (conventional) treatment. In the control group, patients bite cotton balls and gauze, which is the usual method of wound dressing. At postoperative 1 hour, 24 hours and 7 days, hemorrhage (bleeding), comfort and healing levels are evaluated. The adhesion time of oral adhesive bandages is also recorded. For every participant, the study lasts for one week.

What are the possible benefits and risks of participating?
Participants will benefit from discounts on surgery costs. There are risks of allergy towards oral adhesive bandages.

Where is the study run from?
Hospital of Stomatology, Wuhan University (China)

When is the study starting and how long is it expected to run for?
January 2022 to December 2023

Who is funding the study?
The Department of Oral and Maxillofacial Surgery, Hospital of Stomatology, Wuhan University (China)

Who is the main contact?
Dr. Zhou Xiaocheng, zhouxiaocheng@whu.edu.cn (China)

Contact information

Type(s)
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Clinical trial to evaluate the effectiveness and safety of oral adhesive bandage for extraction wound management

Acronym
EASOOABFEWM

Study objectives
The oral adhesive bandages are better than the conventional methods in hemostatic, healing and comforting effects on extraction wound management.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 25/03/2022, The Medical Ethics Committee in the Hospital of Stomatology, Wuhan university (237 Luoyu Road, Hongshan district, Wuhan, 430079, China; +86 027-87686250; wdkqllwyh@163.com), ref: 2022-C12

Study design
Randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Dental clinic, Hospital

Study type(s)
Safety, Efficacy

Participant information sheet
Not available in web format

Health condition(s) or problem(s) studied
Wound management in tooth extraction

Interventions
Patients in the control group bite cotton balls and gauze, while patients in the study group use oral adhesive bandages for extraction socket protection. Bleeding, comforting and healing levels of all patients are measured. The lottery method will be used for randomization.

Participant's journey and follow-up:
Screen, blood test, enrol and randomize, written informed consent, surgery, assess at postoperative 1 hour, assess at postoperative 24 hours, follow up and assess at postoperative 7 days.

A single dentist performed extraction surgeries for all participants, another dentist assessed all participants without knowing their group. The hemostatic measures were performed individually after every extraction surgery. The hemostatic measures were performed upon extraction sockets.

Intervention Type
Device

Pharmaceutical study type(s)
Not Applicable

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Oral adhesive bandages

Primary outcome measure
1. Bleeding measured using a visual examination at 1 and 24 hours postoperative
2. Comfort level measured using a comfort rating scale 1-hour postoperative
3. Healing measured using a visual examination on postoperative day 7
4. Adhesion time of the oral adhesive bandages measured using a visual examination when oral adhesive bandages fall off

Secondary outcome measures
1. Complications measured using patient self-reporting records within 7 days after surgery
2. The duration of extraction surgeries measured using recorded timekeeping from the beginning of surgery to the tooth is extracted

Overall study start date
01/01/2022

Completion date
31/12/2023

Eligibility

Key inclusion criteria
1. Aged between 18-65 years old
2. Requiring surgical removal of one single tooth (except upper and lower third molars)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Both

Target number of participants
120

Key exclusion criteria
1. Menstruation
2. Pregnancy or lactation
3. Periodontitis
4. Tobacco usage
5. Coagulation disorders
6. Infection or immune dysfunction
7. A history of allergy to any drugs
8. Cyst or tumor
9. Unwillingness to participate

Date of first enrolment
01/04/2022

Date of final enrolment
01/12/2023

Locations

Countries of recruitment
China

Study participating centre
Hospital of Stomatology, Wuhan university
237 Luoyu Road
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Sponsor information

Organisation
Wuhan University

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Sponsor type
Hospital/treatment centre

Website
https://whuss.com/article/8258

ROR
https://ror.org/033vjfk17

Funder(s)

Funder type
University/education

Funder Name
Wuhan University

Alternative Name(s)
, WHU

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
China

Results and Publications

Publication and dissemination plan
Planned publication in a high impact peer-reviewed international journal

Intention to publish date
31/12/2023

Individual participant data (IPD) sharing plan
The datasets generated and analysed during the current study will be published as a supplement to the results publication.

IPD sharing plan summary
Published as a supplement to the results publication