

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

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| <b>Submission date</b><br>29/10/2023   | <b>Recruitment status</b><br>No longer recruiting | <input type="checkbox"/> Prospectively registered<br><input type="checkbox"/> Protocol            |
| <b>Registration date</b><br>20/11/2023 | <b>Overall study status</b><br>Completed          | <input type="checkbox"/> Statistical analysis plan<br><input checked="" type="checkbox"/> Results |
| <b>Last Edited</b><br>30/01/2026       | <b>Condition category</b><br>Oral Health          | <input type="checkbox"/> Individual participant data  |

## 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)

Public, Scientific

### Contact name

Dr Xiaocheng Zhou

### ORCID ID

<https://orcid.org/0000-0002-1726-952X>

### Contact details

Department of Oral and Maxillofacial Surgery

School & Hospital of Stomatology

237 Luoyu Road

Hongshan District

Wuhan

China

430079

+8617762401922

zhouxiaocheng@whu.edu.cn

### Type(s)

Principal investigator

### Contact name

Prof Jihong Zhao

### ORCID ID

<https://orcid.org/0000-0001-8857-7557>

### Contact details

Department of Oral and Maxillofacial Surgery

School & Hospital of Stomatology

237 Luoyu Road

Hongshan District

Wuhan

China

430079

+8613607122535

jhzha0988@whu.edu.cn

## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

**ClinicalTrials.gov (NCT)**

Nil known

**Protocol serial number**

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

### Study type(s)

Efficacy, Safety

### 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

**Phase**

Not Applicable

**Drug/device/biological/vaccine name(s)**

Oral adhesive bandages

**Primary outcome(s)**

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

**Key secondary outcome(s)**

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

**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

**Healthy volunteers allowed**

No

**Age group**

Mixed

**Lower age limit**

18 years

**Upper age limit**

65 years

**Sex**

All

**Total final enrolment**

0

**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

Hongshan district

Wuhan

China

430079

**Sponsor information****Organisation**

Wuhan University

**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

## 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

## Study outputs

| Output type                     | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---------------------------------|---------|--------------|------------|----------------|-----------------|
| <a href="#">Results article</a> |         | 07/04/2024   | 30/01/2026 | Yes            | No              |