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# Comparing treatments to stop bleeding in patients: A clinical study of local bleeding control methods

**Submission date**
23/05/2025

**Recruitment status**
No longer recruiting

**Registration date**
29/05/2025

**Overall study status**
Completed

**Last Edited**
02/09/2025

**Condition category**
Oral Health

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

## Plain English summary of protocol

Background and study aims
Some people take medications like aspirin or warfarin to prevent blood clots, but these medicines can make it harder to stop bleeding after a tooth is removed. This study looked at two special dressings—Surgicel and Gelfoam—that help stop bleeding. The goal was to see which one works better at controlling bleeding and helping the gums heal after tooth extraction in people taking these medications.

Who can participate?
Adults aged 40 to 75 years who are taking a daily dose of aspirin (80 mg) or warfarin can take part. People on warfarin must have stable blood test results (INR between 2 and 3.5). Participants must need simple tooth extractions (not complex surgery) and agree not to change their medication during the study.

What does the study involve?
Each participant had two similar teeth removed—one on each side of the mouth. One side was treated with Gelfoam and the other with Surgicel to stop the bleeding. Researchers then checked how much bleeding occurred, how well the gums healed, and how much pain the person felt. These checks were done on day 3 and day 7 after the extraction, and bleeding was also checked 24 hours after the procedure.

What are the possible benefits and risks of participating?
Participants may benefit from close monitoring and care after their tooth extractions. The study could also help improve treatment for others in the future. Risks are similar to those of a normal tooth extraction, such as bleeding, pain, or infection, but all participants were carefully monitored.

Where is the study run from?
University of Damascus (Syria)

When is the study starting and how long is it expected to run for?
November 2022 to December 2024.

Who is funding the study?
University of Damascus (Syria)

Who is the main contact?
Walaa Ali AL-Suliman, Walaa2.alsuliman2@damascusuniversity.edu.sy

# Contact information


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Public, Principal investigator

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# Additional identifiers

### Protocol serial number
5033

# Study information

### Scientific Title
Comparative study of local haemostatic agent on hemorrhagic patients (clinical study)

### Study objectives
This study aims to evaluate and compare the effectiveness of Gelfoam and Sergocel in controlling bleeding in patients taking aspirin and warfarin, to ensure safe and effective solutions for bleeding control during dental extraction procedures. The study also seeks to fill the knowledge gap in the use of hemostatic agents in patients with blood clotting disorders by providing clinical data that can contribute to improving therapeutic practices and selecting the optimal dressing for each case, thus enhancing the quality of care provided to patients at risk of bleeding.

### Ethics approval required
Ethics approval required

### Ethics approval(s)
Approved 16/11/2022, The Institutional Biomedical Research Ethics Committee (Damascus University , Damascus, -, Syria; -; vice.research@damascusuniversity.edu.sy), ref: DN-150525-H27

### Primary study design
Interventional

### Study design
Comparative clinical study

### Study type(s)
Treatment, Efficacy

### Health condition(s) or problem(s) studied
Preventing the risk of bleeding in patients taking the anticoagulants aspirin and warfarin

### Interventions
A clinical study was conducted on 40 patients, divided into two groups based on the type of anticoagulant used (aspirin or warfarin). Each patient received treatment with different

hemostatic dressings: Gelfoam was applied to one side and Surgicel to the other. Bleeding was assessed using the VIBe scale, and the rate of gingival healing was measured using the Gingival Healing Index (GHI) on days three (D3) and seven (D7). Pain was also assessed using the Visual Analogue Scale (VAS), and late bleeding rates were analyzed 24 hours after extraction.

### Intervention Type
Procedure/Surgery

### Primary outcome(s)
1. Bleeding severity is measured using the VIBe scale at baseline, day 3, and day 7
2. Gingival healing is measured using the Gingival Healing Index (GHI) at day 3 and day 7
3. Pain intensity is measured using the Visual Analogue Scale (VAS) at baseline, day 3, and day 7
4. Late bleeding occurrence is measured using clinical observation at 24 hours after extraction

### Key secondary outcome(s)
There are no secondary outcome measures

### Completion date
22/12/2024

## Eligibility

### Key inclusion criteria
1. Age between 40 and 75 years.
2. Patients use aspirin at a daily dose of 80 mg or oral warfarin.
3. Patients using warfarin must have a stable INR value within the therapeutic range (2-3.5) [23].
4. Obtaining written informed consent from all participants, with their commitment to maintaining the anticoagulant doses unchanged throughout the study period.
5. Requirement for simple tooth extractions of paired teeth, without the need for complex surgical intervention.

### Participant type(s)
Population

### Healthy volunteers allowed
No

### Age group
Senior

### Lower age limit
40 Years

### Upper age limit
75 Years

### Sex
All

### Total final enrolment

40

### Key exclusion criteria
1. Presence of uncontrolled systemic diseases that contraindicate tooth extraction.
2. Participation in other clinical trials during the study period is necessary to avoid treatment overlap and influence on results.
3. Unstable INR, where patients with fluctuations in INR outside the required therapeutic range (2-3.5) before extraction or during follow-up were excluded.
4. Severe alcohol or tobacco dependence due to their negative effects on wound healing post-extraction

### Date of first enrolment
16/11/2022

### Date of final enrolment
16/12/2023

## Locations

### Countries of recruitment
India

Iran

Iraq

Jordan

Kuwait

Lebanon

Morocco

Syria

### Study participating centre
**Damascus University**
Faculty of Dentistry
Mezzeh district
Damascus
Syria
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### Study participating centre
**Al-Mowasat University Hospital**
Department of Oral and Maxillofacial Surgery

Damascus
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-

## Sponsor information

### Organisation
Damascus University

### ROR
https://ror.org/03m098d13

## Funder(s)

### Funder type
University/education

### Funder Name
Damascus University

### Alternative Name(s)
University of Damascus, , DU

### Funding Body Type
Government organisation

### Funding Body Subtype
Universities (academic only)

### Location
Syria

## Results and Publications

### Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request:
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## IPD sharing plan summary

Available on request

## Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | | 01/09/2025 | 02/09/2025 | Yes | No |
| Other unpublished results | | | 28/05/2025 | No | No |
| Statistical Analysis Plan | | | 28/05/2025 | No | No |