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Efficacy of various hemostatic agents in relieving post-extraction pain in warfarin patients

Submission date
28/12/2023

Recruitment status
No longer recruiting

Registration date
29/12/2023

Overall study status
Completed

Last Edited
09/08/2024

Condition category
Oral Health

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

Plain English summary of protocol

Background and study aims
Getting a tooth pulled is a common dental procedure, but it can lead to issues like pain, inflammation, and infection. Dentists aim to prevent these complications. Pain after a tooth extraction is often the main problem, affecting a person's quality of life, especially in the first few days. It's crucial to find ways to ease pain and improve a patient's quality of life during the recovery period. The formation of a blood clot is vital for healing because it triggers the necessary immune response. If the clot is dislodged, healing can be delayed and very painful, especially in the first hours after extraction.

This study explores the use of a gelatin-based hemostatic agent called Gelfoam, introduced in 1945, and tranexamic acid (TXA), a known anti-bleeding agent. TXA helps form a stable blood clot in the extraction site when applied topically, minimizing systemic effects. Warfarin, an anticoagulant drug, poses challenges for patients needing tooth extraction, as it may result in uncontrollable bleeding and postoperative pain. The research compares the effectiveness of TXA-soaked Gelfoam and Gelfoam soaked in saline solution in reducing postoperative pain in warfarin patients undergoing tooth extraction.

Who can participate?
1. Patients taking warfarin.
2. International Normalized Ratio (INR) ranges between 2.0 to 3.5.
3. Patients aged 45-70 years.
4. Patients requiring bilateral simple extraction of mandibular teeth.

What does the study involve?
This study was a thorough and rigorous clinical trial employing a randomized, triple-blinded, multicenter, split-mouth design with an active control group. Thirty patients meeting specific criteria were enrolled, and a total of 60 lower jaw teeth slated for simple extraction were included. The patients were randomly assigned to two groups for post-extraction treatment:
Control Group (Group 1):
- Hemostatic agent used: Gelfoam sponge (SURGISPON®, Aegis Lifesciences, Gujarat, India)

soaked in sterile saline solution (SODIUM CHLORIDE 0.9% MIAMED, Miamed Pharmaceutical Industry, Damascus, Syria) (n = 30)
2. Study Group (Group 2):
- Hemostatic agent used: TXA-soaked absorbable Gelfoam (TXA-Gel) (Trenekop, Kopran Ltd, Haryana, India) (n = 30)

The trial was triple-blinded, meaning the investigator, participants, and outcome assessor were unaware of the treatment assignment. Randomization was performed using a simple coin flip. The patients' baseline information, medical and dental histories were documented, and clinical and radiological examinations were conducted. The International Normalized Ratio (INR) level was assessed before extraction to ensure it was suitable for minor surgery. Local anesthesia was administered, and bilateral tooth extraction was performed with minimal trauma by a skilled surgeon, adhering to asepsis and antisepsis principles. After extraction, Gelfoam soaked in tranexamic acid was applied in the study group, while Gelfoam soaked in saline solution was applied in the control group. Sockets were closed using a figure-of-8 suturing technique with 3.0 silk sutures.

What are the possible benefits and risks of participating?
The possible benefit is the extraction of non-restorable and infected teeth. The possible risk is postoperative pain due to the questionable effect of the involved materials.

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

When is the study starting and how long is it expected to run for?
November 2021 to October 2023

Who is funding the study?
Damascus University (Syria)

Who is the main contact?
Dr Mawia Karkoutly, Mawiamaherkarkoutly@hotmail.com

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Protocol serial number
Funder No. 501100020595

Study information

Scientific Title
Efficacy of topical tranexamic acid soaked absorbable Gelfoam in relieving post-extraction pain in warfarin patients: A randomized, triple-blinded, multicenter, split-mouth, active-controlled clinical trial

Study objectives
The null hypothesis was that no statistically significant difference would be noted in the efficacy of the topical application of TXA-soaked absorbable Gelfoam (TXA-Gel) and Gelfoam sponge soaked in sterile saline solution in relieving postoperative pain following bilateral simple extraction of mandibular teeth in warfarin patients.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 08/11/2021, The Biomedical Research Ethics Committee (Mazzeh Highway, Damascus, -, Syria; +963 (11) 33923223; dean.dent@damascusuniversity.edu.sy), ref: N4041

Primary study design
Interventional

Study design
Randomized triple-blinded multicenter split-mouth active-controlled clinical trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Relieving postoperative pain following simple extraction of mandibular teeth in warfarin patients

Interventions
This was a randomized, triple-blinded, multicenter, split-mouth, active-controlled clinical trial. Based on the inclusion criteria, 30 patients were recruited. 60 bilateral mandibular teeth which were indicated for simple extraction in 30 patients randomly assigned into two groups according to the topical hemostatic agents after extraction used:
Group 1: control group, Gelfoam sponge (SURGISPON®, Aegis Lifesciences, Gujarat, India) soaked in sterile saline solution (SODIUM CHLORIDE 0.9% MIAMED, Miamed Pharmaceutical Industry, Damascus, Syria) (n = 30)
Group 2: TXA-soaked absorbable Gelfoam (TXA-Gel) (Trenekop, Kopran Ltd, Haryana, India) (n = 30)
This was a triple-blinded trial, where the investigator, the study participants, and the outcome assessor were blinded to the treatment allocation. A simple randomization method was

performed by flipping a coin.
The patient's baseline demographic data and their medical and dental history were recorded. The clinical and radiological examination was performed, and the level of the INR was determined before dental extraction using a self-testing instrument (CoaguChek® XS system, Roche Diagnostics, Indiana, USA) to ensure that it is at the appropriate level for minor surgery. Local anesthesia was administered at the site of extraction by depositing 2% lidocaine with epinephrine 1:80,000 solution (2% Lidocaine HCL Injection, Huons Co., Ltd, Seongnam, Korea) using a dental carpule syringe (Dental carpule syringe, Dental Laboratorio, Guangdong, China) and a 27-gauge x ¾ inch needle (Disposable Dental Needles, J Morita, Connecticut, United States). Bilateral extraction was carried out with the least possible trauma by a single experienced surgeon at the same appointment. Extraction was performed according to asepsis and antisepsis rules. The sockets were thoroughly irrigated and rinsed to remove follicular tissue and debris after extraction. A Gelfoam sponge sized (10x10x10 mm) was soaked in tranexamic acid (500mg/5mL) and then applied immediately after extraction in the sockets of the study group. A Gelfoam sponge soaked in sterile saline solution was also applied immediately after extraction in the sockets of the control group. Sockets closed by performing figure-of-8 suturing technique using 3.0 silk sutures (TUDOR® DVR-4942, Champion Biotech & Pharma Corp., Manila, Philippines).

Intervention Type
Procedure/Surgery

Primary outcome(s)
The intensity of pain was evaluated on the 1st (t1), 2nd (t2), 3rd (t3), 4th (t4), 5th (t5), 6th (t6), and 7th (t7) day following extraction and hemostatic agents application using Visual Analogue Scale (VAS)

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

Completion date
25/10/2023

Eligibility

Key inclusion criteria
1. Patients taking warfarin.
2. International Normalized Ratio (INR) ranges between 2.0 to 3.5.
3. Patients aged 45-70 years.
4. Patients requiring bilateral simple extraction of mandibular teeth.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
45 Years

Upper age limit
70 Years

Sex
All

Total final enrolment
30

Key exclusion criteria
1. Smoking patients.
2. Patients with coagulopathies.
3. Patients with uncontrolled diabetes mellitus.
4. Patients are allergic to any anesthetic agent.
5. Patients with temporomandibular joint disorders.

Date of first enrolment
13/01/2023

Date of final enrolment
05/10/2023

Locations

Countries of recruitment
Syria

Study participating centre
Department of Oral and Maxillofacial Surgery, Faculty of Dentistry, Damascus University
Mazzeh Highway
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Syria
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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 will be available upon request from Dr Mawia Karkoutly, Mawiamaherkarkoutly@hotmail.com. The type of data that will be shared is currently not known. The timing for availability is upon a reasonable request. Informed consent was obtained.

Comments on data anonymization: N/A
Any ethical or legal restrictions: N/A
Any additional comments: N/A

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		07/08/2024	09/08/2024	Yes	No
Protocol file			29/12/2023	No	No