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Investigating tranexamic acid for bleeding control in facelift surgery

Submission date	**Recruitment status**	[_] Prospectively registered
01/11/2025	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
06/11/2025	Ongoing	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
06/11/2025	Surgery	[X] Record updated in last year

Plain English summary of protocol

Background and study aims
This randomized controlled trial investigates whether local tranexamic acid (TXA) can reduce intraoperative bleeding and postoperative complications (like hematoma, swelling, and bruising) in patients undergoing facelift (rhytidectomy) surgery at King Abdulaziz University Hospital. TXA is known for minimizing bleeding in surgery, but no RCT has evaluated its local use in facelifts.

Who can participate?
Healthy adults aged 35 years and older, or those with stable (compensated) medical conditions, who are undergoing facelift surgery.
People are excluded if they are under 35, have bleeding or clotting disorders, take anticoagulants or hormones, or have major organ failure.

What does the study involve?
Participants are randomly assigned to either:
Intervention group: receive local TXA under the skin flap, or
Control group: receive standard care (lidocaine with epinephrine only).
Bleeding is measured during surgery, and participants attend three follow-up visits (days 1, 6, and 9) and one remote check. Surgeons and patients rate bruising and swelling at each visit.

What are the possible benefits and risks of participating?
Benefits: TXA may reduce bleeding, bruising, swelling, and overall complications, leading to faster recovery.
Risks: Rare allergic or clotting reactions, nausea, low blood pressure, rash, or visual disturbances. Pregnant or breastfeeding individuals must not participate.

Where is the study run from?
Conducted at King Abdulaziz University Hospital (KAUH), Riyadh, Saudi Arabia, under King Saud University supervision.

When is the study starting and how long is it expected to run for?
February 2024 to June 2026

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Principal Investigator:
Prof. Ahmad Al-Arfaj, aalarrfaj@ksu.edu.sa

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
E-23-8441

Study information

Scientific Title
Effects of local tranexamic acid on bleeding during rhytidectomy and post operative complication: randomized, controlled, single-blind trial

Acronym
TXA-Rhytid Trial

Study objectives
Determine whether Local TXA has any effect on intraoperative bleeding or postoperative sequelae in patients undergoing a facelift.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 19/02/2024, College of Medicine Institutional Review Board (King Saud University – College of Medicine, Riyadh, 11472, Saudi Arabia; +966 114670011; irbresearch2@gmail.com), ref: E-23-8441

Study design
Interventional single blind randomized controlled trial

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied

Prevention of bleeding and postoperative complication in Rhytidectomy

Interventions
Control: Tumescent (0.5% lidocaine with 1:200,000 epinephrine).
Case: Tranexamic acid (TXA) +Tumescent (1 mg/ml TXA and 0.5% lidocaine with 1:200,000 epinephrine)
Administration Rout: Local Infiltration
Randomization of allocation: by using random numbers table generated in the Statistical Package for Social Studies (SPSS v. 21) (SPSS v. 21, IBM Corp., New York, NY, USA)
The total duration of treatment and follow-up will be 1 month

Intervention Type
Drug

Phase
Phase III/IV

Drug/device/biological/vaccine name(s)
Tranexamic acid

Primary outcome(s)
Certainly, Nicholas. Here's the revised list of outcome measures in the correct format:

1. Intraoperative blood loss is measured using the volume collected in the surgical suction container during surgery
2. Intraoperative blood loss is measured using gravimetric analysis by weighing surgical sponges and gauze before and after use during surgery
3. Postoperative edema is measured using a subjective 3-point scale (mild, moderate, severe) assessed by both patient and surgeon at postoperative visits 1, 6, and 9
4. Postoperative ecchymosis is measured using a subjective 3-point scale (mild, moderate, severe) assessed by both patient and surgeon at postoperative visits 1, 6, and 9
5. Postoperative edema is measured using objective volumetric assessment with Vectra imaging at postoperative visits 1, 6, and 9
6. Postoperative ecchymosis is measured using objective volumetric assessment with Vectra imaging at postoperative visits 1, 6, and 9

Key secondary outcome(s))
1. Patient satisfaction is measured using the FACE-Q questionnaire at baseline (before procedure) and postoperative day 9
2. Time to drain removal is measured using clinical records at end of study
3. Complications will be assessed at follow up visits:
- Skin necrosis
- Hematoma
- Thromboembolic events
- Infection

Completion date
01/06/2026

Eligibility

Key inclusion criteria
1. ≥ 35-year-old
2. Capable for follow up
3. Healthy patients or with compensated comorbidities, after the agreement of the assigned health care team
4. Candidates for cosmetic face and neck surgery
5. Absence of previous surgeries on the face

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
35 years

Upper age limit
75 years

Sex
All

Key exclusion criteria
1. < 35-year-old
2. History of thromboembolic events or seizure
3. History of bleeding disorder
4. Active use of oral contraceptive pills and/or hormone replacement therapy, Aspirin, anti-coagulant, and Omega 3
5. Patient preference
6. Any condition increase edema (Renal failure, heart failure, liver disease)

Date of first enrolment
01/05/2024

Date of final enrolment
01/05/2026

Locations

Countries of recruitment
Saudi Arabia

Study participating centre
King Abdulaziz University Hospital, King Saud University
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Sponsor information

Organisation
King Saud University

ROR
https://ror.org/02f81g417

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date