

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

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Study protocol

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Abstract

Background

Rhytidectomy carries a substantial risk of bleeding, which may lead to complications such as hematoma formation, compromised cutaneous vascular supply, and prolonged recovery. Recent clinical discussions and reports have described the use of tranexamic acid (TXA) in rhytidectomy, and this practice is increasingly appearing in literature. Hematoma remains one of the most common complications following rhytidectomy. Several studies have reported on the safety profile and potential efficacy of TXA in minimizing postoperative sequelae; however, most studies evaluating local TXA in facelift surgery are observational. To our knowledge, no randomized controlled trial protocol has been published assessing local TXA combined with tumescent solution compared with tumescent solution alone in facelift surgery. This trial may support evidence-based practice, improve patient outcomes, and contribute to cost-effective care.

Methods

This protocol describes a single-blind randomized controlled trial at King Abdulaziz University Hospital in Riyadh that will enroll patients undergoing rhytidectomy. The control arm will receive standard tumescent solution (0.5% lidocaine with 1:200,000 epinephrine). The intervention arm will receive TXA (1 mg/mL) added to the same tumescent solution. Both regimens will be administered intraoperatively via local infiltration under the skin flap.

Discussion

This trial is designed to evaluate whether local TXA in rhytidectomy reduces bleeding-related outcomes without increasing complications. The results may support a simple, cost-effective practice change; however, generalizability may be limited by the single-center, single-blind design.

Trial registration:

ISRCTN17892023, Registration date 06/11/2025, Retrospectively registered.

Introduction

Background and rationale {9a}

Facelift procedures are one of the most performed cosmetic surgeries in the United States [1–2].

Bleeding is a substantial risk during rhytidectomy, which may lead to hematoma formation, cutaneous vascular compromise, and extended recovery. There are many risk factors for hematoma formation, including hypertension, anticoagulant use, coagulopathy, male gender, excess postoperative physical activity, and postoperative nausea and vomiting [3]. TXA is an anti-fibrinolytic agent it reduces bleeding by inhibiting the conversion of plasminogen to plasmin, therefore preventing the enzymatic degradation

of fibrin clots [4]. Its preventive use has been studied in different surgical procedures, and it has proven effectiveness in reducing intraoperative bleeding [5, 6].

Evidence suggests TXA may reduce hematoma risk and postoperative drainage in facelift and related plastic surgery procedures. Schroeder et al. [3] and Serrano et al. [7] reported fewer minor hematomas and marked reductions in drain output, while Yildirim et al. [8] also found lower hematoma incidence. Additional studies in plastic surgery (Scarafoni et al. [9], Tiourin et al. [10]) support TXA's role in reducing bleeding, and Kochuba et al. [11] and Couto et al. [12] reported lower postoperative drainage volumes in TXA groups, including when combined with adjunct haemostatic measures.

A recent systematic review and meta-analysis reported that TXA significantly reduces minor hematomas and postoperative drain output without increasing major complications, and may also reduce intraoperative blood loss, ecchymosis, and edema, highlighting the need to clarify the optimal route and dosing [13]. Following this meta-analysis, a retrospective matched study conducted on a large sample size found that local TXA (1–2 mg/mL) was not associated with differences in wound-healing complications in facelifts with wide undermining, which challenges the consistency of TXA's benefit on reducing hematoma [14]. A rhytidectomy protocol based on 40 years' experience described a multistep hematoma-prevention approach with improved hematoma rates, but its retrospective nature, lack of a control group, and use of adjunctive measures, fibrin glue, and hemostatic nets, limit interpretation [15]. Notably, the first RCT assessing intravenous TXA in rhytidectomy found a statistically significant reduction in postoperative collections, while blood loss, patient-rated ecchymosis, and edema were comparable; however, this trial primarily evaluated the IV route, and additionally, bleeding, edema, and ecchymosis were assessed subjectively [16]. Moreover, a recent RCT assessed whether IV or local TXA is the optimal administration route for patients undergoing rhytidectomy and found that both groups had equivalent ecchymosis and edema ratings, median blood scores, and complication rates [17]. Our trial focuses on topical TXA compared to tumescent with standardized outcome assessment. Collectively, these findings highlight persisting gaps in the evidence regarding the optimal TXA route and its true effect on bleeding related outcomes in rhytidectomy, our protocol aims to address these gaps through a randomized design with standardized, well-defined outcome assessment.

Explanation for the choice of comparator {9b}

The comparator was chosen because it represents the current standardized care used in literature and our setting for rhytidectomy to support haemostasis, ensuring participants in the control arm receive the usual accepted management.

Objectives {10}

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

Methods: Patient and public involvement, and trial design

Patient and public involvement {11}

No patient/public involvement in the design or conduct of this trial is described in the protocol. Participants will take part as study subjects via informed consent.

Trial design {12}

This study is designed as a randomized controlled, single-blind, with two parallel arms and a 1:1 allocation ratio. Participants will be randomized using computer-generated randomization software to receive either standard care tumescent solution control or TXA with tumescent solution intervention. Participants will remain blinded to treatment allocation, and the analysis will be performed according to the intention-to-treat principle.

Methods: Participants, interventions and outcomes

Trial setting {13}

Hospital-based trial conducted at King Abdulaziz University Hospital (KAUH), Riyadh, Saudi Arabia.

Characteristics of the people who are needed for the trial

Characteristic	The people we would expect to see included
Age	Adults ≥ 35 years undergoing facelift/rhytidectomy.
Sex	Male and Female facelift candidates
Gender	Man and Woman
Race, ethnicity and ancestry	Not specified
Socioeconomic status	Not specified
Geographic location	Riyadh, Saudi Arabia (single site: King Abdulaziz University Hospital)
Other characteristics relevant to the trial	

Eligibility criteria for participants {14a}

Inclusion criteria: ≥ 35 years old; capable for follow-up; healthy or with compensated comorbidities after agreement of the assigned healthcare team; candidates for cosmetic face and neck surgery; no previous facial surgeries.

Exclusion criteria: < 35 years old; history of thromboembolic events or seizure; history of bleeding disorder; active use of oral contraceptive pills and/or hormone replacement therapy, aspirin, anticoagulants, and omega-3; patient preference; any condition that increases edema (renal failure, heart failure, liver disease).

Eligibility criteria for sites and those delivering interventions {14b}

ORL-HNS Department team performing rhytidectomy and delivering intervention; include surgeons performing the procedure.

Who will take informed consent? {32a}

Written informed consent will be obtained by a designated member of the study team during the first preoperative clinic visit. The study will be explained verbally and in writing, and participants will have the opportunity to ask questions before signing the consent form.

Additional consent provisions for collection and use of participant data and biological specimens {32b}

N/A

Intervention and comparator

Intervention and comparator description {15a}

- Comparator (control): Control: Tumescant (0.5% lidocaine with 1:200,000 epinephrine), administered intraoperatively by the surgical team.
- Intervention: TXA +Tumescant (1 mg/ml TXA and 0.5% lidocaine with 1:200,000 epinephrine).
- Administration Rout: Local Infiltration applied under the skin flap.

Criteria for discontinuing or modifying allocated intervention/comparator {15b}

The allocated intervention/comparator will be discontinued or modified if continuation is considered clinically unsafe (suspected serious adverse event or significant adverse reaction), if a new contraindication is identified after enrolment, or if the participant requests withdrawal at any time. In

such cases, the participant will receive standard care, and the reason for discontinuation/modification will be documented.

Strategies to improve adherence to intervention/comparator {15c}

N/A

Concomitant care permitted or prohibited during the trial {15d}

Participants with active use of oral contraceptives or hormone replacement therapy, blood thinners (aspirin, anticoagulants), or omega-3 are excluded.

Ancillary and post-trial care {34}

No rewards/incentives are provided; compensation for harm is covered by hospital insurance.

Outcomes {16}

Primary

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

Secondary outcomes:

1. 1. Patient satisfaction is measured using the FACE-Q questionnaire at baseline (before procedure) and postoperative day 9 [18].
2. 2. Time (day) to drain removal is measured using clinical records at end of study less than 25 ml.
3. 3. Complications will be assessed at follow up visits:
 - - Skin necrosis.
 - - Hematoma.

- - Thromboembolic events.
- - Infection.

Harms {17}

Anticipated/potential harms listed

- Severe allergic reaction which may include a red and lumpy skin rash, difficulty breathing, swelling of face, mouth, lips or eyelids, unexplained high temperature (fever) and feeling faint.
- Symptoms of a blood clot which may include swelling or pain in your legs or chest, headache, weakness of the face and limbs on one side of the body.

How harms will be assessed

Assessed clinically via postoperative clinic visits and remote follow-up to exclude any complications. Adverse events will be assessed by the study team, and participants will have direct contact with the principal investigator for any inquiries or questions. All harms recorded in the trial will be reported in publications.

Participant timeline {18}

When a potential participant is scheduled for the procedure, the participant will be informed about the study and written informed consent will be obtained at the preoperative visit. At the same visit, a medical history and physical examination will be performed, and routine laboratory investigations will be obtained, including complete blood count (CBC), coagulation profile, renal function tests (RFT), and liver function tests (LFT). After consent, participants will be randomized to the study groups. The surgical procedure will then be performed according to standard practice. Postoperative follow-up will take place in the clinic on Day 1, Day 6, and Day 9. A remote follow-up phone contact will be conducted at Day 30 to assess late complications and confirm recovery status. Participant flow and the timing of study procedures and outcome assessments are presented using the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) Figure [19] (Fig. 1).

Sample size {19}

The sample size was calculated based on an assumed standard deviation (SD) of 0.152 and a mean difference of 0.26, with a two-sided alpha level of 0.01 and 95% power. Based on these assumptions, the required sample size is 28 participants. To account for an anticipated attrition rate of 15%, the final target sample size will be 32 participants, with 16 participants allocated to each arm. (11)

Recruitment {20}

Participants will be recruited from adults scheduled to undergo facelift surgery at the study site. All potentially eligible patients will be screened for inclusion, and those who meet eligibility criteria will be

approached for participation. Written informed consent will be obtained from all participants prior to enrolment, and a total of 32 participants will be recruited (16 control and 16 intervention).

Assignment of interventions: randomisation

Sequence generation: who will generate the sequence {21a}

Computer-generated randomisation 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) will be used; will be performed by the designated author.

Sequence generation: type of randomisation {21b}

Simple randomisation 1:1 (one-to-one).

Allocation concealment mechanism {22}

The randomisation sequence will be concealed from the clinical and research team responsible for recruitment and follow-up to minimize selection bias. Allocation will be disclosed only after the participant has been enrolled and assigned a study ID, with access to the randomisation list restricted to the designated author; participants will remain blinded to their group allocation throughout the study.

Implementation {23}

The designated author will maintain the randomisation list and will assign participants to the intervention groups after enrolment. The staff involved in recruitment and outcome assessment will not have access to the randomisation sequence.

Assignment of interventions: blinding

Who will be blinded {24a}

This is a single-blind trial; participants will be blinded to treatment allocation throughout the study procedure.

How will be blinding be achieved {24b}

Blinding will be maintained by concealing the allocation within the randomization system. Participants will not be informed of their assigned group.

Procedure for unblinding if needed {24c}

Unblinding will be done only if clinically necessary for participant safety. The primary investigator will access the allocation code and document the reason, time, and the person unblinded.

Data collection and management

Plans for assessment and collection of outcomes {25a}

The trial staff will collect baseline characteristics, study outcome, and adverse events will be record in the study dataset using standardized data collection procedures. Outcome assessment will include the primary and secondary outcomes, will be assessed as described in detail in the methodology section.

Plans to promote participant retention and complete follow-up {25b}

Follow-up will take place in the hospital and will be aligned with planned postoperative clinic visits on days 1, 6, and 9, so additional retention strategies are not anticipated. Participants may withdraw from the trial at any time. No further data will be collected unless the participant provides permission, in all cases the participant's wishes will be respected.

Data management {26}

All authorized staff will be trained in data collection protocol and Good Clinical Practice (GCP). Data will be recorded through Electronic Case Report Forms (eCRF) to support data control; the access will be restricted to authorized users via individual accounts/passwords and regular audits will be conducted by Clinical Trail Unit (CTU) to verify compliance with the protocol and GCP.

Confidentiality {33}

The study will maintain participant confidentiality and anonymity. Participants will be identified using a coded study ID to protect privacy, and any identification file will be stored in a password-protected secure folder on the institution's network. Access to identifiable information and study records will be restricted to authorized members of the research team only, and all analyses and reporting will use de-identified data.

Statistical methods

Statistical methods for primary and secondary outcomes {27a}

Analyses will be performed using SPSS (v26 or later). Continuous outcomes will be assessed for normality. If normally distributed, results will be presented as mean with (SD) and between-group differences will be tested using Student's t-test. If not normally distributed, results will be presented as

median with interquartile range (25–75%) and between-group differences will be tested using the Mann–Whitney U test. Categorical outcomes will be summarized as frequencies and percentages and compared using Pearson’s chi-square test or Fisher’s exact test, as appropriate. Ordinal outcomes (3-point edema and ecchymosis scales) will be summarized as frequencies/percentages by category and compared using appropriate ordinal/non-parametric methods. Repeated postoperative assessments (Day 1, Day 6, and Day 9) will be analyzed using methods appropriate for repeated measures. Effect estimates will be presented with two-sided 95% confidence intervals. Statistical significance will be set at $\alpha = 0.05$.

Who will be included in each analysis {27b}

The primary analysis will follow the intention-to-treat principle, including all randomized participants (1:1) analyzed in the groups to which they were allocated. A per-protocol analysis will be conducted as a sensitivity analysis, excluding predefined major protocol deviations. Safety analyses will include all participants who received any study infiltration and will summarize adverse events and complications by randomized group.

How missing data will be handled in the analysis {27c}

The amount and pattern of missing data will be summarized. The primary analysis will be performed using an intention-to-treat approach. If missingness for the primary outcome is minimal, a complete-case analysis will be used; if missingness is non-trivial, multiple imputation under a missing-at-random assumption will be applied, with sensitivity analyses to assess robustness.

Methods for additional analyses (e.g. subgroup analyses) {27d}

No subgroup analyses are planned. Adjusted analyses may be performed if clinically important baseline imbalances are observed, using prespecified baseline variables.

Interim analyses {28b}

No interim efficacy analysis is planned due to the small sample size.

Safety will be monitored during routine postoperative visits, and the Principal Investigator may pause or terminate the trial if unexpected serious safety concerns occur.

Protocol and statistical analysis plan {5}

Following study completion, analysis, and publication, the trial protocol will be available through the journal. The anonymized participant-level dataset and statistical code will be available from the Principal

Investigator on reasonable request.

Oversight and monitoring

Composition of the coordinating centre and trial steering committee {3d}

King Abdulaziz University Hospital (KAUH), Riyadh, Saudi Arabia, will serve as the coordinating center. The trial steering group will consist of the Principal Investigator, co-investigators, a study coordinator, and the trial statistician. The coordinating center will maintain day-to-day contact to support trial conduct, with structured meetings held regularly to review recruitment, protocol adherence, data completeness, and safety signals.

Composition of the data monitoring committee, its role and reporting structure {28a}

This is not applicable. No independent data monitoring committee will be constituted, given the limited risk of the intervention, the relatively small sample size. Trial safety oversight will be performed by the Principal Investigator through routine postoperative assessments and reporting to the institutional ethics committee/IRB according to local requirements.

Frequency and plans for auditing trial conduct {29}

The trial will be audited and monitored by the CTU in accordance with institutional policies, ethics approval conditions, and Good Clinical Practice standards. Any monitoring/auditing findings requiring corrective actions will be documented and addressed by the coordinating center.

Protocol amendments {31}

All substantial amendments will be submitted to the IRB and Clinical trial unit for approval prior to implementation and updated in the trial registry when applicable. Where relevant, participants will be informed of protocol changes that may affect their participation.

Dissemination policy {8}

Publications will only contain anonymised data. We aim to publish the main results of the trial in a peer-reviewed journal.

Discussion

From a practical standpoint, successful completion of this single center randomized trial will depend on enrolling an adequate number of eligible elective facelift patients and maintaining consistent perioperative practice, so that any observed differences are attributable to the allocated intervention. Recruitment will be integrated into the routine preoperative clinic workflow, and the operative team will follow a standardized protocol for preparation and intraoperative administration of the allocated solution. Maintaining the single-blind design will require that allocation is documented using coded group labels and is not disclosed to participants. Complete outcome assessment relies on timely follow-up on postoperative days 1, 6, and 9, supplemented by remote phone contact; therefore, visits will be aligned with standard postoperative appointments and reinforced with reminders as needed.

Trial status

Recruitment started on 01/05/2024, and recruitment is expected to be completed by approximately 01/06/2026.

Abbreviations

- **TXA**

Tranexamic acid

- **RCT**

Randomized controlled trial

- **KAUH**

King Abdulaziz University Hospital

- **KSU**

King Saud University

- **IRB**

Institutional Review Board

- **ORL-HNS**

Otorhinolaryngology–Head and Neck Surgery

- **CBC**

Complete blood count

- **RFT**

Renal function tests

- **LFT**

Liver function tests

- **SPSS**

Statistical Package for the Social Sciences

- **GCP**

Good Clinical Practice

- **CTU**

Clinical Trial Unit

- **eCRF**

Electronic Case Report Forms

- **SD**

standard deviation

- **SPIRIT**

Standard Protocol Items:Recommendations for Interventional Trials

- **Face-Q**

FACE-Q questionnaire

Declarations

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The institution King Saud University Medical City as participating site of this clinical trial.

Authors’ contributions {3a}

AO, A.Al-arfaj, and A.Al-Enazi, will perform the surgical procedures, follow-up, and clinical assessments. LRB is the trial manager. A.Alderaywsh, LRB, OA, and A.Alrabiah will perform patient recruitment. LRB, A.Alderaywsh, A.Alrabiah, and OA drafted the manuscript. All authors contributed to the establishment of the protocol, revised the manuscript, and provided input according to their area of expertise.

Sources of funding and other support {7a}

No funding was obtained for this study. This is a Primary investigator-initiated study and did not receive external funding. The authors have applied for an institutional publication support award from Ministry of Education to cover article processing charges; the outcome is pending. The award will have no role in the study design, data collection, analysis, interpretation, or reporting of results.

Availability of data and materials {6}

Not Applicable

Ethics approval and consent to participate {30}

This study protocol was approved by the IRB at King Saud University’s College of Medicine, approval number E-23-8441. It is also registered as an international standard randomized control trial, registration number ISRCTN17892023; registered on 6th of November 2025. All participants will sign a written consent form prior to enrolment in this trial.

Consent for publication

Not applicable.

Competing interests {7b}

The authors declare that they have no competing interests.

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Figures

	TRIAL PERIOD					
	Enrollment		Post-randomization			Close-out
TIMEPOINT ^b	$-t_i$ to 0 (Preoperative Visit)	0 (Surgery)	t_1 (POD1)	t_2 (POD6)	t_3 (POD9)	t_x (POD30)
ENROLLMENT:						
Eligibility screen	X					
Informed consent	X					
Baseline (History, Physical examination, Labs)	X					
Randomization	X					
INTERVENTION/ COMPARATOR:						
TXA + Tumescant		X				
Tumescant without TXA		X				
ASSESSMENTS:						
Intraoperative blood loss		X				
Edema and ecchymosis			X	X	X	
Drain output		X	X	X	X	
Face-Q	X				X	
Complications		X	X	X	X	X

Figure 1

Participant timeline: Schedule of enrollment, interventions, and assessments.^a

Abbreviations: FACE-Q, FACE-Q questionnaire; TXA, tranexamic acid.