STUDY PROTOCOL

Official Title
The Effect of Visual Aids Used in Addition to the Informed Consent Form on Understanding of Consent and Level of Anesthesia Awareness in Patients Attending the Anesthesia Outpatient Clinic

Brief Title
Effect of Visual Aids Added to Informed Consent on Patient Understanding and Anesthesia Awareness

Clinical Trial Registration
Registry: ClinicalTrials.gov
NCT Number: Pending (to be assigned)

Protocol Version
Version 1.0

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Study Design

Prospective, single-center, cluster-randomized, parallel-group, single-blinded (outcome assessor–blinded), controlled interventional study.

Study Period

Planned Start Date: May 1, 2026
Planned Completion Date: September 1, 2026

Estimated Study Duration: 4 months

Study Sponsor / Responsible Institution

Dr. Abdurrahman Yurtaslan Ankara Oncology Training and Research Hospital
Department of Anesthesiology and Reanimation
Ankara, Türkiye

Study Location

Anesthesia Outpatient Clinic
Dr. Abdurrahman Yurtaslan Ankara Oncology Training and Research Hospital
Ankara, Türkiye

Background and Rationale

Informed consent is a fundamental ethical and legal requirement that ensures patients make voluntary decisions based on adequate and comprehensible medical information. Anesthesia-related procedures involve complex processes and rare but serious complications, making effective communication particularly critical.

Previous literature has demonstrated that standard written informed consent forms frequently exceed average patient health literacy levels and may not ensure true comprehension. Studies indicate that patients often have limited understanding of anesthesia techniques, potential complications, and rare but ethically significant risks.

Visual and multimedia-supported educational tools have been shown to improve comprehension, reduce cognitive load, and enhance recall of medical information. However, limited data exist regarding structured infographic-supported consent processes evaluated through validated outcome measures within a cluster-randomized design to minimize contamination bias.

This study aims to address this methodological and clinical gap.

Study Objective

To evaluate whether providing visual aid–supported information in addition to the standard written informed consent form improves:

1. Patient understanding of informed consent
2. Anesthesia knowledge level
3. Awareness of anesthesia-related risks

4. Overall anesthesia awareness

Hypotheses

Null Hypothesis (H0):
There is no difference between patients receiving visual aid–supported informed consent and those receiving standard written consent alone in terms of anesthesia knowledge, risk awareness, consent comprehension, or perceived adequacy of information.

Alternative Hypothesis (H1):
Patients receiving visual aid–supported informed consent will demonstrate significantly higher anesthesia knowledge, risk awareness, consent comprehension, and perceived adequacy of information compared to those receiving standard written consent alone.

Study Population

Adult patients presenting to the anesthesia outpatient clinic for elective surgery evaluation.

Inclusion Criteria

- Age ≥ 18 years
- Able to read and understand Turkish
- Scheduled for elective surgery
- Willing to participate in the study

Exclusion Criteria

- Age < 18 years
- Emergency surgery
- Cognitive impairment
- Severe visual or hearing impairment preventing communication
- Refusal to participate

Sample Size

Sample size was calculated using G*Power 3.1.9.7 for independent group comparison:

- Effect size (Cohen’s d): 0.5

- Alpha (Type I error): 0.05
- Power (1-β): 0.90

Initial required sample: 172 patients (86 per group).

Considering cluster randomization:

- Mean cluster size: 10
- ICC: 0.02
- Design effect: 1.18

Adjusted sample size: 203 patients.

Accounting for 15% potential attrition:
Final planned sample size: **236 patients** (approximately 118 per group).

Randomization and Allocation

Cluster randomization will be applied to minimize contamination risk.

- Patients will be grouped into clusters of 10 consecutive participants.
- Each cluster will be randomly assigned to:
    - Control Group
    - Intervention Group
- Each cluster will receive only one intervention type.
- Multiple group interventions will not be conducted simultaneously on the same day.

Interventions

Control Group

Standard written anesthesia informed consent form + standardized verbal explanation by the same anesthesiologist.

Intervention Group

Standard written anesthesia informed consent form + structured visual aid–supported educational material + standardized verbal explanation by the same anesthesiologist.

All information sessions will be conducted:

- By the same anesthesiology specialist
- Using identical core verbal content
- In the same outpatient clinic environment

Outcome Measures

Primary Outcome

Informed Consent Comprehension Score
Measured 30 minutes after the information session using a structured questionnaire.

Secondary Outcomes

- Anesthesia Knowledge Score
- Anesthesia-Related Risk Awareness Score
- Total Knowledge Score
- Perceived Adequacy of Information (Likert-based scale)

Data Collection Instrument

A structured questionnaire developed based on the institution's standard anesthesia consent form.

Structure:

1. Demographic and clinical characteristics
2. 20 objective knowledge questions (True / False / I don't know)
3. 10 Likert-type items evaluating perception of information adequacy and awareness

Content validity was established through expert review (Academic Test Committee approval dated January 16, 2026).

Blinding

Single-blind design:

- Outcome assessor blinded to group allocation

- Questionnaire administered by an anesthesiologist not involved in the information session
- Questions read via standardized audio recording to avoid tone-related bias
- Administered in a quiet, distraction-free setting

Statistical Analysis

Data will be analyzed using SPSS (IBM SPSS Statistics) or equivalent software.

Descriptive statistics:

- Continuous variables: Mean ± SD or median (min–max)
- Categorical variables: Frequency and percentage

Comparative analysis:

- Independent t-test or Mann–Whitney U test (continuous variables)
- Chi-square or Fisher's exact test (categorical variables)

Statistical significance threshold: $p < 0.05$

Ethical Considerations

- Ethics Committee approval will be obtained prior to study initiation.
- Participation is voluntary.
- Written informed consent will be obtained from all participants.
- Personal data will be anonymized.
- Data will be stored securely for 5 years in accordance with regulations.

Budget

Stationery and printing costs: 1000 TL
No external funding.

Study Center

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