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Monitoring sedation depth with brain wave monitors during emergency procedures

Submission date 06/10/2026	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 06/10/2026	**Overall study status** Completed	
Last Edited 06/10/2026	**Condition category** Surgery	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Study information

Scientific Title
Assessment of procedural sedation depth with bispectral ındex in the emergency department: a randomized controlled, double-blind study

Study objectives

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 27/01/2022, Ataturk University Faculty of Medicine Clinical Research Ethics Committee (Ataturk Mah., Ataturk University Campus, Yakutiye, Erzurum, 25240, Türkiye; +90 (0) 442 234 65 11; atatipetikkurul@gmail.com), ref: B.30.2.ATA.0.01.00/97

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Active

Assignment
Parallel

Purpose
Device feasibility, Supportive care, Treatment

Study type(s)

Health condition(s) or problem(s) studied
Procedural sedation and analgesia in adult emergency department patients requiring procedural sedation for painful interventions.

Interventions
Eligible participants presenting to the emergency department who require procedural sedation and analgesia (PSA) are randomly allocated to one of two parallel groups using sealed, sequentially numbered envelopes:
1. Propofol-Fentanyl Group (Group 1): Participants receive intravenous (IV) propofol (maximum 1 mg/kg) combined with IV fentanyl (1 mcg/kg)
2. Propofol-Midazolam Group (Group 2 - Active Control): Participants receive intravenous (IV) propofol (maximum 1 mg/kg) combined with IV midazolam (0.05 mg/kg)

To ensure blinding, study medications are prepared in identical sealed syringes by an independent provider. Half of the total calculated dose is administered as an initial IV bolus, followed by gradual titration at 2–3-minute intervals if target moderate sedation is not achieved, without exceeding the predetermined maximum dose limit.

Before drug administration, single-use Bispectral Index Monitor (BIS; Aspect BIS Vista monitor / Aspect Medical Systems / Covidien-Medtronic) electrodes are placed on the forehead, and non-

invasive hemodynamic monitoring (blood pressure, heart rate, pulse oximetry, and respiratory rate) is initiated. Baseline (minute 0) BIS and vital parameters are recorded. During the reduction procedure, BIS values, clinical sedation depth (assessed via verbal and tactile stimuli by a blinded observer), and vital signs are recorded minute by minute. Monitoring continues until participants return to their baseline cognitive levels (standardized as a BIS score ≥ 90 and return of orientation).

Intervention Type
Drug/Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Propofol (propofol), fentanyl (fentanyl citrate), midazolam (midazolam hydrochloride), bispectral index monitor

Primary outcome(s)
1. Depth of procedural sedation measured using bispectral Index (BIS) monitoring (Aspect BIS Vista monitor) at minute-by-minute timepoints from the procedure start (minute 0) until the end of procedure, and minimum BIS value recorded during the procedure

Key secondary outcome(s)

Completion date
01/01/2023

Eligibility

Key inclusion criteria
1. Patients aged between 18 and 65 years
2. Presenting to the emergency department and requiring procedural sedation and analgesia (PSA) for closed reduction of extremity fractures or dislocations
3. Able to read, understand, and write in Turkish
4. American Society of Anesthesiologists (ASA) Physical Status Class I or Class II
5. Provision of written informed consent by the patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
65 Years

Sex

All

Total final enrolment
91

Key exclusion criteria
1. Patients younger than 18 or older than 65 years of age
2. Known allergy or hypersensitivity to any of the study medications (propofol, fentanyl, or midazolam)
3. American Society of Anesthesiologists (ASA) Physical Status Class ≥ 3 or ASA Class E according to ICAPS criteria
4. Uncontrolled diabetes mellitus, uncontrolled hypertension, or serious underlying cardiac or chronic pulmonary disease
5. Identified risk for difficult airway or high risk for pulmonary aspiration
6. Pregnancy or breastfeeding
7. Indications requiring minimal/dissociative sedation only or general anesthesia
8. Pre-existing cognitive dysfunction or inability to give informed consent
9. Impaired skin integrity in the frontal/forehead region preventing BIS sensor placement

Date of first enrolment
01/02/2022

Date of final enrolment
07/11/2022

Locations

Countries of recruitment
Türkiye

Sponsor information

Organisation
Atatürk University

ROR
https://ror.org/03je5c526

Funder(s)

Funder type

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available