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Evaluation of remimazolam for safe and effective dental sedation in patients with cognitive disabilities

Submission date
05/11/2025

Recruitment status
No longer recruiting

Registration date
10/11/2025

Overall study status
Completed

Last Edited
10/11/2025

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
This study investigates the use of remimazolam besylate, a short-acting sedative medication, for intravenous sedation during dental treatments in adults with cognitive or neurodevelopmental disabilities. Many people with such conditions experience anxiety, involuntary movements, or difficulties cooperating during dental care, making conventional treatment challenging or even impossible. The research aims to evaluate how safe and effective remimazolam is when used to help these patients undergo dental procedures comfortably and without complications.

Who can participate?
Adult patients classified as ASA II or III.

What does the study involve?
Each participant received intravenous remimazolam under close anesthetic supervision. Researchers assessed how quickly sedation started, how stable patients' vital signs remained during the procedure, how long recovery took, and whether any side effects occurred. They also measured the ability to complete the planned dental treatment without the need for additional medication or general anesthesia.

What are the possible benefits and risks of participating?
By analyzing these results, the study aims to provide evidence that remimazolam offers a safe, effective, and predictable alternative to other sedative drugs for people with cognitive disabilities who require dental care.

Most participants experience a safe and well-tolerated procedure. However, as with any form of intravenous sedation, there are some possible risks. These may include temporary drowsiness, light-headedness, or delayed reaction times after the procedure. Less commonly, changes in breathing, blood pressure, or heart rate may occur, although in this study, no cases of hypoxemia or serious complications were reported. Mild side effects such as nausea, vomiting, or headache

may also occur in a small number of patients. All sedation is provided by trained clinicians using continuous monitoring to ensure participant safety, and any adverse effects are managed promptly.

Where is the study run from?
Fondazione IRCCS Ca' Granda Ospedale Maggiore Policlinico in Milan, Italy.

When is the study starting and how long is it expected to run for?
July 2024 to July 2025

Who is funding the study?
Investigator initiated and funded.

Who is the main contact?
Dr Matteo Pellegrini, matteo.pellegrini@unimi.it

Contact information

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Public, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Trial ID 4996

Study information

Scientific Title
Efficacy of remimazolam besylate for intravenous sedation in dental procedures for patients with cognitive disabilities: a prospective cohort study

Acronym
SED-REMIDIS

Study objectives
Primary objective:
To evaluate the efficacy and safety of intravenous remimazolam besylate for procedural sedation during outpatient dental treatments in adult patients with cognitive disabilities.

Secondary objectives:
- To assess the onset time of sedation, recovery time, and discharge readiness following remimazolam administration.
- To evaluate hemodynamic and respiratory stability throughout the dental procedure.
- To record the total remimazolam dose required to achieve adequate sedation (according to Narcotrend and clinical response).
- To document the incidence and severity of any adverse events (e.g., hypoxemia, hypotension, nausea, vomiting).
- To evaluate postoperative recovery using the Modified Aldrete Score (MAS) and the Post-Anesthetic Discharge Scoring System (PADSS).

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 17/07/2024, Lombardy 3 Territorial Ethics Committee (Via Francesco Sforza 28, Milan, 20122, Italy; +39 02 5503.2982; federica.massacesi@policlinico.mi.it), ref: 4996_17.07.2024_P_bis

Study design
Prospective single-centre observational cohort study

Primary study design
Observational

Study type(s)
Efficacy

Health condition(s) or problem(s) studied
Adult patients with cognitive or neurodevelopmental disabilities (e.g., intellectual disability, autism spectrum disorder, cerebral palsy) who require dental procedures that cannot be performed under conventional conditions, thus necessitating intravenous sedation for safe and effective care.

Interventions
All participants received intravenous procedural sedation with remimazolam besylate administered by an anesthesiologist during outpatient dental treatment.
Sedation was induced with a starting dose of 2.5–5 mg, followed by incremental boluses of 2.5 mg as required to achieve the desired level of sedation (Narcotrend stages D–E).
Throughout the procedure, spontaneous ventilation was maintained and hemodynamic and respiratory parameters were continuously monitored (ECG, SpO_2, NIBP, respiratory rate).
No additional sedatives or flumazenil reversal were used.
Post-procedural recovery was assessed using the Modified Aldrete Score (MAS) and the Post-Anesthetic Discharge Scoring System (PADSS).

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Remimazolam besylate [Byfavo®]

Primary outcome(s)
Procedural success rate is measured using data extracted from patient medical records at the end of the dental procedure, defined as the ability to complete the dental treatment under remimazolam sedation alone with adequate clinical sedation, maintenance of spontaneous ventilation, and no adverse events requiring intervention.

Key secondary outcome(s))
1. Onset time of sedation: Onset time of sedation is measured in minutes using the Ramsay Sedation Scale (target score = 4) assessed intraoperatively from the initial administration of remimazolam.
2. Recovery time: Recovery time is measured in minutes from the end of remimazolam administration to the achievement of full clinical recovery, assessed post-procedure through direct clinical observation of the patient’s return to baseline responsiveness, orientation, and spontaneous motor activity.
3. Hemodynamic and respiratory stability: Hemodynamic and respiratory stability are measured using continuous anesthetic monitoring of blood pressure, heart rate, SpO_2, and respiratory rate recorded throughout the intraoperative period.
4. Adverse events: Adverse events are measured using clinical observation and medical record documentation intraoperatively and post-procedure, and include the incidence and type of sedation-related complications (e.g., hypoxemia, hypotension, nausea, vomiting).
5. Postoperative discharge readiness: Postoperative discharge readiness is measured using both the Post-Anesthetic Discharge Scoring System (PADSS) and the Modified Aldrete Score (MAS),

with readiness defined as PADSS ≥ 8 and MAS ≥ 9, assessed immediately before discharge from the dental unit.

Completion date
25/07/2025

Eligibility

Key inclusion criteria
1. Adult patients aged 18 years or older with a diagnosis of cognitive or neurodevelopmental disability (including intellectual disability, autism spectrum disorder, or cerebral palsy) who require outpatient dental treatment under intravenous sedation
2. Classified as ASA physical status II or III
3. Had a stable medical condition
4. Deemed suitable for procedural sedation according to the institutional protocol
5. Written informed consent obtained from the caregiver or legal guardian before inclusion

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
80 years

Sex
All

Total final enrolment
43

Key exclusion criteria
1. Severe systemic diseases corresponding to ASA physical status IV or higher
2. Unstable cardiovascular or respiratory conditions
3. Known hypersensitivity to benzodiazepines or remimazolam components, or a history of adverse reactions to sedative agents.
4. Significant hepatic or renal impairment
5. Active respiratory infection
6. Pregnancy or breastfeeding
7. Those receiving medications known to interfere with benzodiazepine metabolism
8. Whose caregivers or legal guardians were unable to provide informed consent

Date of first enrolment

07/01/2025

Date of final enrolment
25/07/2025

Locations

Countries of recruitment
Italy

Study participating centre
Fondazione IRCCS Ca' Granda Ospedale Maggiore Policlinico
Via Francesco Sforza, 35
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Sponsor information

Organisation
Fondazione IRCCS Ca' Granda Ospedale Maggiore Policlinico

ROR
https://ror.org/016zn0y21

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
Individual participant data will not be publicly shared because the study population includes adults with cognitive disabilities, and the anonymisation of detailed clinical data cannot guarantee full protection of privacy. However, aggregated and de-identified summary data supporting the main findings will be available upon reasonable request to the corresponding

author and with approval from the Fondazione IRCCS Ca' Granda Ospedale Maggiore Policlinico. The study documentation, including statistical analyses and datasets, will be stored securely in accordance with institutional data protection policies and the European General Data Protection Regulation (GDPR).

Name and email address of the investigator/body who should be contacted for access to the datasets: Dr Matteo Pellegrini, matteo.pellegrini@unimi.it

Type of data that will be shared: Only aggregated and fully de-identified summary data related to the primary and secondary outcomes will be shared. Due to the vulnerability of the study population (adults with cognitive disabilities), individual participant data (IPD) will not be publicly shared, as full anonymization cannot guarantee protection against re-identification.

Timing for availability: Summary datasets will be available after publication of the main study manuscript and will remain available upon reasonable request for at least 5 years.

Whether consent from participants was required and obtained: Written informed consent was obtained from caregivers or legal guardians, including permission for the use of anonymized data for research and publication purposes.

Comments on data anonymization: All shared data will undergo de-identification in compliance with GDPR and institutional data protection policies.
Direct identifiers (names, dates of birth, contact information) will be removed, and indirect identifiers will be masked or generalized. Dates will be shifted and unique codes applied to minimize any risk of re-identification.

Any ethical or legal restrictions: Because the population includes individuals with cognitive or neurodevelopmental disabilities, ethical and legal considerations limit the sharing of raw IPD.

Access to anonymized summary datasets will require:
• A reasonable, scientifically sound proposal
• Approval from the Principal Investigator
• Signing of a controlled data-sharing agreement compliant with GDPR

Any additional comments: No biological samples or imaging files will be shared. Only anonymized summary-level datasets and the associated data dictionary will be accessible.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 2.0	03/10/2024	10/11/2025	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes