CONSORT 2010 Checklist for Randomized Controlled Trials

Study Title: Non-Inferiority Trial of Remimazolam vs. Propofol for Fast-Track Anesthesia in Congenital Heart Disease Patients

Based on: Schulz KF, Altman DG, Moher D, et al. CONSORT 2010 Statement: Updated guidelines for reporting parallel group randomized trials.

Section/Topic	Item No.	Checklist Item	Reported on Page No.
Title and Abstract	1a	Identification as a randomized trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions	1–2
Introduction	2a	Scientific background and explanation of rationale	2–3
	2b	Specific objectives or hypotheses	3
Methods	3a	Description of trial design (such as parallel, non-inferiority, randomized)	4
	3b	Important changes to methods after trial commencement, with reasons	N/A
Participants	4a	Eligibility criteria for participants	4–5

	4b	Settings and locations where the data were collected	4
Interventions	5	The interventions for each group with sufficient details to allow replication	5
Outcomes	6a	Clearly defined primary and secondary outcome measures	5–6
	6b	Any changes to trial outcomes after the trial commenced, with reasons	N/A
Sample Size	7a	How sample size was determined	4
	7b	When applicable, explanation of any interim analyses and stopping guidelines	N/A
Randomization	8a	Method used to generate the random allocation sequence	5
	8b	Type of randomization; details of any restriction (such as blocking, stratification)	5
Allocation Concealment Mechanism	9	Mechanism used to implement random allocation sequence (e.g., opaque envelopes)	5

Implementation	10	Who generated the sequence, who enrolled participants, and who assigned interventions	5
Blinding (Masking)	11a	Who was blinded after assignment to interventions and how	5
	11b	If relevant, description of the similarity of interventions	5
Statistical Methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	6–7
	12b	Methods for additional analyses (e.g., subgroup, adjusted analyses)	N/A
Results	13a	Participant flow (numbers assigned, treated, and analyzed)	Figure 1
	13b	Losses and exclusions after randomization, with reasons	Figure 1
Recruitment	14a	Dates defining recruitment and follow-up periods	4
	14b	Why the trial ended or was stopped	4

Baseline Data	15	A table showing baseline demographic and clinical characteristics for each group	Table 1
Numbers Analyzed	16	Number of participants (denominator) in each analysis	7
Outcomes and Estimation	17a	Results for each primary and secondary outcome, with effect size and precision	7–9
	17b	For binary outcomes, presentation of both absolute and relative effect sizes	8
Ancillary Analyses	18	Results of any other analyses performed, distinguishing pre-specified from exploratory	N/A
Harms	19	All important harms or unintended effects in each group	7–8
Discussion	20	Trial limitations, addressing sources of potential bias, imprecision, and multiplicity	10–11
	21	Generalizability (external validity, applicability) of the trial findings	11

	22	Interpretation consistent with results, balancing benefits and harms	10–12
Other Information	23	Registration number and name of trial registry	2, 12
	24	Where the full trial protocol can be accessed, if available	Upon request from corresponding author
	25	Sources of funding and other support	12
	26	Ethical approval and consent to participate	12

Additional Notes

Trial Registration: ChiCTR2500109737 (Chinese Clinical Trial Registry)

Registration date: 24 September 2025

Ethics Approval: Zhengzhou University Central China Fuwai Hospital Ethics Committee (Approval No. 37/2024)

Adherence: The study was conducted and reported in accordance with the CONSORT 2010 guidelines.