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ORIGINAL RESEARCH

Evaluating the effect of perioperative carbohydrate loading on reducing the incidence of PONV in middle ear surgery: a multi-arm randomised controlled trial

Supplementary file:

CONSORT 2010 checklist of information to include when reporting a randomised trial

Checklist for reporting of multi-arm, parallel-group randomised trials: extension of the CONSORT 2010 Statement

Section/topic	Item no.	Checklist item	Reported on page no.
Title and abstract			
	1a	Identification as a multi-arm, randomised trial in the title or an indication of the number of treatment groups that the participants were randomly assigned to	Title page
	1b	Specification of the number of treatment groups; details of any groups added or dropped	1
Introduction			
Background and objectives	2a	Rationale for using a multi-arm design	3
	2b	Specification of the research question referring to all the treatment groups Clear statement of all hypotheses to be tested and the primary comparisons involved	3
Methods			
Trial design	3a	Specification of the number of treatment groups	4
	3b	Details of any treatment groups added or dropped (if relevant), with reasons and/or changes to the allocation ratio	None
Participants	4a	Eligibility criteria for participants	4
	4b	Settings and locations where the data were collected	4
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	4, 5
Outcomes	6a	Completely defined prespecified primary and secondary outcome measures, including how and when they were assessed	5, 6
	6b	Any changes to trial outcomes after the trial commenced, with reasons	None
Sample size	7a	Planned sample size with details of how it was determined for each primary comparison	6
	7b	When applicable, explanation of any interim analyses and stopping guidelines	None
Randomisation			
Sequence generation	8a	Method used to generate the random allocation sequence	4
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	4
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	4
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	4
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	4, 5
	11b	If relevant, description of the similarity of interventions	4, 5
Statistical methods	12a	Explicitly state if no adjustments for multiplicity were applied; if adjustments were applied, state the method used	6
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	None
Results			
Participant flow (a diagramme is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	7
	13b	For each group, losses and exclusions after randomisation, together with reasons	7

Recruitment	14a	Dates defining the periods of recruitment and follow-up (if periods of recruitment and follow-up are different across treatment groups, e.g. groups were added or dropped, the periods of recruitment and follow-up, reason/s for the differences, and any statistical implications should be described)	4
	14b	Why the trial ended or was stopped	NA
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Table I
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	7
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval) Results for each prespecified comparison of treatment groups	7
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	7
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing prespecified from exploratory	None
Harms	19	All important harms or unintended effects in each group (for specific guidance, see CONSORT for harms)	None
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	9
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	8, 9
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	8, 9
Other information			
Registration	23	Registration number and name of trial registry	Tile page, 4
Protocol	24	Where the full trial protocol can be accessed, if available	9
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	Title page