

CONSORT 2010 Checklist – Completed for Manuscript Submission

Title: Petroleum Jelly vs. Saline in Tracheostomy Wound Care and Ulcer Prevention: A Randomized Controlled Trial

Corresponding Author: Dr. Kanokrat Bunnag

Journal: BMC Surgery

Checklist completed based on the final submitted manuscript.

Item No	Checklist Item	Reported on Page No / Comments
1a	Identification as a randomized trial in the title	Title page
1b	Structured summary of trial design, methods, results, and conclusions	Page 1 (Abstract)
2a	Scientific background and explanation of rationale	Pages 2–3
2b	Specific objectives or hypotheses	Page 3 (End of Introduction)
3a	Description of trial design (such as parallel, factorial) including allocation ratio	Pages 3–4
3b	Important changes to methods after trial commencement, with reasons	Not applicable
4a	Eligibility criteria for participants	Page 3
4b	Settings and locations where the data were collected	Page 3
5	Interventions for each group with sufficient detail	Pages 4–5
6a	Pre-specified primary and secondary outcome measures	Page 5
6b	Changes to trial outcomes after commencement	Not applicable
7a	How sample size was determined	Page 4
7b	Interim analyses and stopping guidelines	Page 4 – explicitly stated none
8a	Method used to generate the random allocation	Page 4

	sequence	
8b	Type of randomization; details of any restriction	Page 4 (block of 4)
9	Allocation concealment mechanism	Page 4 (sealed, opaque envelopes)
10	Who generated, enrolled, and assigned participants	Page 4
11a	Blinding after assignment to interventions	Page 5 (outcome assessors blinded)
11b	Similarity of interventions	Not applicable (topical wound care)
12a	Statistical methods used for primary and secondary outcomes	Page 6
12b	Methods for additional analyses	Page 6 – no ancillary analysis performed
13a	Participant flow: assigned, treated, analyzed	Page 7 (all 28 completed)
13b	Losses and exclusions after randomisation	Page 7 (none reported)
14a	Recruitment and follow-up dates	Page 3 (Nov 2021 – Dec 2022)
14b	Why the trial ended or was stopped	Not applicable (completed as planned)
15	Baseline demographic and clinical characteristics	Pages 7–8, Table 1
16	Number analyzed in each group	Pages 7–9
17a	Outcomes for each group, effect size and precision	Pages 9–12, Tables 2–3
17b	Absolute and relative effect sizes for binary outcomes	Not applicable (continuous data)
18	Results of other analyses including subgroup and adjusted	Page 6 – not performed
19	All important harms or unintended effects	Page 12 – no adverse events reported
20	Trial limitations	Pages 14–15
21	Generalisability of findings	Page 15
22	Interpretation consistent with results and evidence	Page 14–15
23	Registration number and name of trial registry	Abstract + Page 3 (TCTR20240806002)
24	Where full trial protocol can be accessed	Page 16, Declarations
25	Sources of funding and role of funders	Page 16, Declarations – no funding