Checklist

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

Section/Topic	Item No	Checklist item	Reported in (headings)
Title and abstract			
	1a	Identification as a randomised trial in the title	Title page (Pg 1, Line 3-5)
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	Abstract section (Pg 3, Line 35-56)
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	Introduction section, paragraphs 1-2 (Pg 7, Line 127-145)
	2b	Specific objectives or hypotheses	Introduction section, paragraphs 3 (Pg 7-8, Line 146-155)
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	In Methods Section: Trail design: Pg 8, Line 157-159 In Study design section: Allocation ratio: Pg 9-10, Line 194-208
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	**Not applicable**
Participants	4a	Eligibility criteria for participants	In Methods : Patient populations – Pg 8-9, Line 169-181
	4b	Settings and locations where the data were collected	In Methods: First paragraph Pg 8, Line 157-159

Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	In Methods: Treatment section, Pg 9, Line 183-192
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	In Methods: Study assessments section, Pg 11, Line 214-224
	6b	Any changes to trial outcomes after the trial commenced, with reasons	**Not applicable**
Sample size	7a	How sample size was determined	In Methods: Study design and sample size (first paragraph), Pg 10, Line 196-201
	7b	When applicable, explanation of any interim analyses and stopping guidelines	**Not applicable**
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	In study design: Line 198-201 In statistical analysis: Last two lines (236-238), Pg 11-12
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	Study design and sample size section: Pg 10, Line no. 194-201
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	Study design and sample size section: Pg 10, Line no. 194-201
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	In statistical analysis: Last line (Bio-statistician), Line 236-238
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	**Not applicable**
	11b	If relevant, description of the similarity of interventions	**Not applicable**
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	Methods section: Statistical analysis, Pg 11-12, Line 226-238
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	Methods section: Statistical analysis, Pg 11-12, Line 226-238
Results			
	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	Results: Patient disposition; Figure 2

Participant flow (a diagram is strongly recommended)	13b	For each group, losses and exclusions after randomisation, together with reasons	Results: Patient disposition; Figure 2, Pg 12
Recruitment	14a	Dates defining the periods of recruitment and follow-up	Methods: First paragraph Pg 8, Line 157-159
	14b	Why the trial ended or was stopped	**Not applicable**
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Table 1, Pg 13
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	Results: Patient disposition; Figure 2, Pg 12
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: Figure 3 (Pg 14); Table 2 (Pg 15)
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	**Not applicable**
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	**Not applicable**
Harms	19	All-important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	In Results: Safety section-Table 3 (Pg 16-17)
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	Discussion section (Paragraph 7) Line 346-352
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	Discussion: Comparison with conventional formulation, paragraph 1,2,3,4,5 (Line 304-345)
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	Discussion and Conclusion section
Other information			
Registration	23	Registration number and name of trial registry	Between abstract and Plain language summary (Pg 4); Also in Ethical Approval Section (Pg 20).

Protocol	24	Where the full trial protocol can be accessed, if available	URL: https://ctri.nic.in/Clinicaltrials/advsearch2.php https://ctri.nic.in/Clinicaltrials/showallp.php?mid1=2135,11627&EncHid=&userName=Nanosomal%20Paclitaxel%20lipid%20suspension
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	Funding section (Pg 21)