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

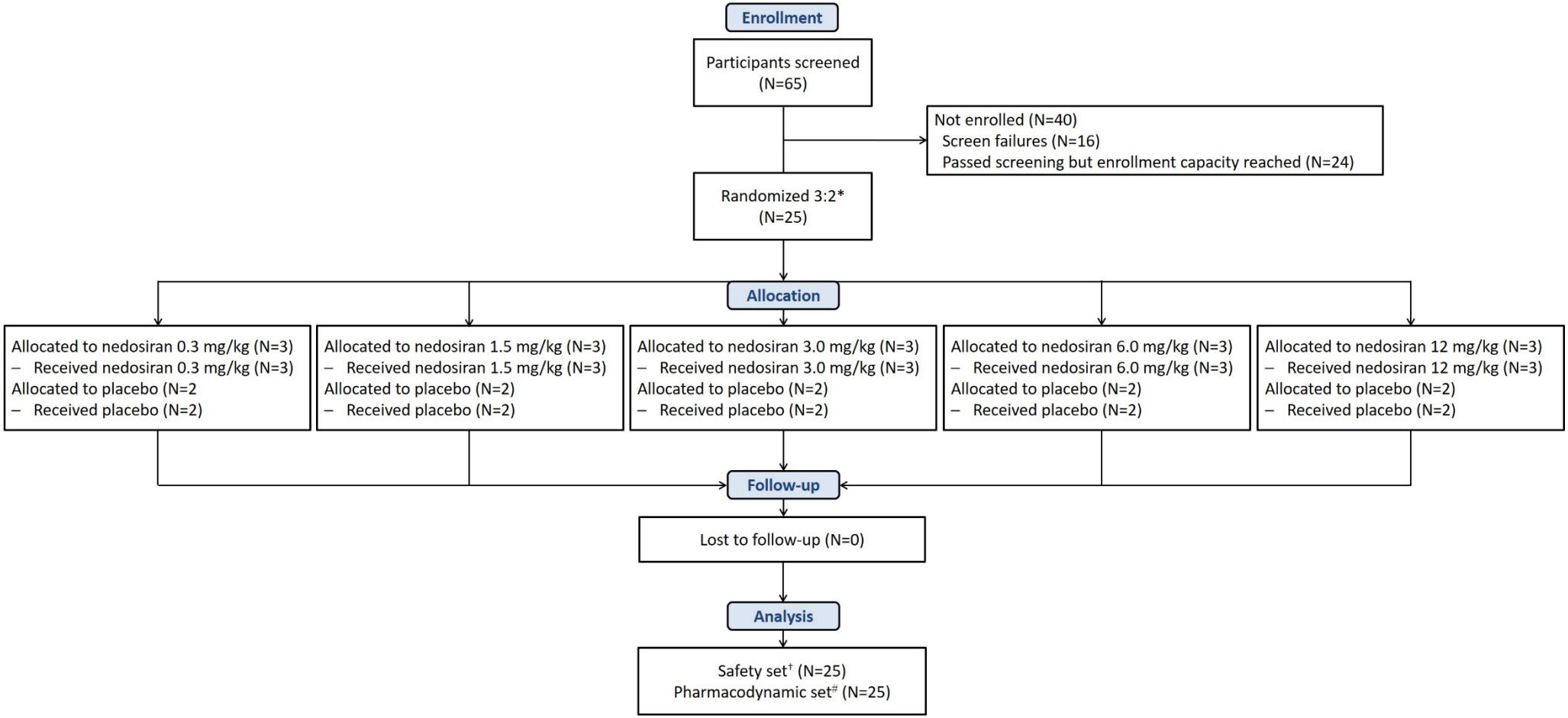
Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	1 NOT APPLICABLE; RCT not the sole source of data in manuscript
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	4 NOT APPICABLE; RCT not the sole source of data in manuscript
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	6-9
	2b	Specific objectives or hypotheses	8-9
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	10-11
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	NOT APPLICABLE
Participants	4a	Eligibility criteria for participants	10-11
	4b	Settings and locations where the data were collected	21
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	10-11, 21
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	10-12
	6b	Any changes to trial outcomes after the trial commenced, with reasons	No
Sample size	7a	How sample size was determined	NOT APPLICABLE; Study not hypothesis driven.

			Sample size considered sufficient to assess safety profile.
	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	21
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	NOT APPLICABLE
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	NOT APPLICABLE
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	NOT APPLICABLE
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	21
	11b	If relevant, description of the similarity of interventions	No
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	12
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	NOT APPLICABLE
Results			
Participant flow (a diagram 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	FLOW DIAGRAM ATTACHED BELOW (PAGE 4)
	13b	For each group, losses and exclusions after randomisation, together with reasons	FLOW DIAGRAM ATTACHED BELOW (PAGE 4)
Recruitment	14a	Dates defining the periods of recruitment and follow-up	10-11, 21
	14b	Why the trial ended or was stopped	NOT APPLICABLE
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	28
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	10,13
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)	13-14
	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)	NOT APPLICABLE
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	17-18
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	17-18
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	15-17
Other information			
Registration	23	Registration number and name of trial registry	10
Protocol	24	Where the full trial protocol can be accessed, if available	10
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	19

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

Flow of participants through the placebo-controlled, single-blind, single ascending dose study of PHYOX1



*All participants were centrally assigned to randomized study intervention using an interactive web response system. The first 2 participants in each cohort received study intervention on the same day (1 active, 1 placebo). After a 3-day observation period, if deemed safe and tolerated (with no medically important adverse events) by the Safety Review Committee, the remaining participants in the cohort were randomized (2 active: 1 placebo) and received study intervention.

†The safety set included all participants who received a full or partial dose of study medication.

#The pharmacodynamic set included all participants who received a full dose of study drug, who did not have any major protocol deviations that may have invalidated or biased the results, and did not use a concomitant medication which rendered the pharmacodynamic assessments unreliable.