SPIRIT | CONSORT CHILDREN & ADOLESCENTS
Reporting Guidelines for Child Health Trials

CONSORT-C 2026

Item 6.3: Introduction – Background and Rationale

Include a description of the research question or aim with a justification for undertaking the trial in children/adolescents

Title and abstract	1a.1	Title and structured abstract
Introduction	6.1	Background and rationale *Prevalence/incidence*
	6.2	Background and rationale *Efficacy/effectiveness*
	6.3	Background and rationale *Research question or aim*
Methods	12a.1	Eligibility criteria *Justification for including multiple age groups*
	12a.2	Eligibility criteria *Age-appropriate trial information*
	13.1	Intervention and comparator *Dose/formulation*
	13.2	Intervention and comparator *Intervention delivery*
	14.1	Outcomes
	15.1	Harms
Results	25.1	Baseline data
	28.1	Ancillary analyses
Discussion	29.1	Interpretation

Key elements for reporting this item:

- Need for the trial in the context of existing paediatric evidence
- Rationale for including specific age range(s)
- Whether the trial was done for regulatory purposes.

Examples:

"[The sponsor] has developed a bivalent virus-like particle (VLP) vaccine (TAK-214) against norovirus that has been proven to be safe and immunogenic in several clinical studies in adults[reference]. (. . .) As the dose and dosing regimen in young children has yet to be elucidated clinically we performed an age de-escalation study in children in Colombia, Finland and Panama to assess the safety, tolerability and immunogenicity of TAK-214. In this report we present the data from the first part of this study in 1-8-year-old children, in whom we also assessed the optimal dose and dosing regimen of TAK-214."

Vesikari T, Saez-Llorens X, Blazevic V, et al. Immunogenicity of a bivalent virus-like particle norovirus vaccine in children from 1 to 8 years of age: A phase 2 randomized, double-blind study. Vaccine 2022;40:3588-96. doi:10.1016/j.vaccine.2022.04.089

"Heel lancing is one of the most common painful procedures performed among infants admitted to the [neonatal intensive care unit] NICU.[reference] Oral sweet solutions effectively alleviate procedural pain in infants, including the pain during heel lancing, and 24% sucrose is the most commonly used solution.[reference] Despite their remarkable safety profile, sucrose solutions have been constrained by unavailability and cost, especially in resource-limited settings.[reference] Alternatively, oral glucose solutions of varying strengths (10%-50%) have been explored for procedural analgesia and found to be effective.[reference] Only 1 study has given a direct comparison of the analgesic effect of sucrose with glucose among preterm infants in an intensive care setting.[reference] However, the researchers evaluated infants at a mean postnatal age of 21 days. In reality, most painful interventions in preterm infants are usually performed within the first 2 weeks of life.[reference] In addition, the researchers used 20% solutions that are not commercially available.[reference] Therefore, in the current study, we planned to evaluate if 25% dextrose solution is not inferior to 24% sucrose for heel-lance analgesia in preterm infants requiring intensive care."

Sasidharan R, Gupta N, Yadav B, Chawla D, Singh K, Kumarendu Singh A. 25% Dextrose Versus 24% Sucrose for Heel Lancing in Preterm Infants: A Noninferiority RCT. Pediatrics 2022;149:e2021054618. doi:10.1542/peds.2021-054618.

Statement (co-published in *The BMJ, JAMA Pediatrics, and The Lancet Child and Adolescent Health*): Baba A, Smith M, Potter BK, et al. CONSORT-Children and Adolescents (CONSORT-C) 2026 Extension Statement: Enhancing the Reporting and Impact of Paediatric Randomised Trials. BMJ 2026;392:e085061. doi: 10.1136/bmj-2025-085061

Explanation and Elaboration: Baba A, Smith M, Potter BK, et al. CONSORT-C 2026 explanation and elaboration: recommendations for enhancing the reporting and impact of paediatric randomised trials. BMJ 2026;392:e085063. doi: 10.1136/bmj-2025-085063