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

SPIRIT-C 2026

Item 17.1: Harms – Mitigation measures

Describe whether trial interventions and/or procedures will induce fear, pain, distress, or are invasive, and what measures are taken to mitigate this

Administrative information	1a.1	Title and structured summary
Open science	6.1	Data sharing
Introduction	9a.1	Background and rationale *Prevalence/incidence*
	9a.2	Background and rationale *Extrapolation*
	9a.3	Background and rationale *Research question or aim*
Methods	13.1	Trial setting
	14a.1	Eligibility criteria
	15a.1	Intervention and comparator *Dose/formulation*
	15a.2	Intervention and comparator *Adaptations*
	15a.3	Intervention and comparator *Intervention delivery*
	16.1	Outcomes
	17.1	Harms *Mitigation measures*
	17.2	Harms *Efforts to reduce risk*
	20.1	Recruitment *Impact of trial participation*
	20.2	Recruitment *Recognition for trial participation*
Ethics	32a.1	Consent or assent
	34.1	Ancillary and post-trial care

Key elements for reporting this item:

- Efforts taken to reduce pain and distress related to trial interventions or procedures in both the experimental and comparator groups
- Specific strategies that will be used to reduce pain, discomfort, distress, and invasiveness of procedures
- If available, evidence on interventions and procedures used to mitigate or treat any potential harms of participation.

Examples:

"If successfully randomised, the research nurse assists the participant to self-administer 10 successive inhalations of the IMP [investigational medicinal product]. Participants and parents/legal guardians are advised that rescue analgesia is available immediately on request at any time. Permitted rescue medications are intranasal fentanyl, intranasal diamorphine, intranasal ketamine, intravenous morphine, oral morphine or Entonox (50% nitrous oxide and 50% oxygen mixture), dependent on the standard practice of the participating site and at the discretion of the treating clinician. This approach is in line with current recommended practice [reference] for the management of moderate to severe pain. Standard-of-care oral analgesic medications (paracetamol and ibuprofen) may be administered as concomitant medications alongside rescue medication. Participants who report pain relief due to IMP inhalation are advised to continue to self-administer additional inhalations, as required, during their [emergency department] ED attendance . . . Half of the patients recruited to the MAGPIE trial will receive trial treatment in the form of placebo. During the consent process and during the trial training provided by the research nurse, it is emphasised that rescue analgesia is available at any time on request. Furthermore, the treating blinded clinician is trained to assess the patient at the 20-min time point and to consider the need for rescue analgesia if the pain level has not decreased. The research nurse ensures that, before a patient is enrolled, there is a clinician who will be immediately available to prescribe rescue analgesia or, where possible, that the rescue analgesia is drawn up in parallel with the study treatment."

Hartshorn S, Barrett MJ, Lyttle MD, Yee SA, Irvine AT; in collaboration with Paediatric Emergency Research in the UK and Ireland (PERUKI). Inhaled methoxyflurane (Penthrox®) versus placebo for injury-associated analgesia in children-the MAGPIE trial (MEOF-002): study protocol for a randomised controlled trial. Trials 2019;20:393. doi:10.1186/s13063-019-3511-4.

See the E&E for more examples.

Statement (co-published in *The BMJ, JAMA Pediatrics, and The Lancet Child and Adolescent Health*): Baba A, Smith M, Potter BK, et al. SPIRIT-Children and Adolescents (SPIRIT-C) 2026 Extension Statement: Enhancing the Reporting and Usefulness of Paediatric Randomised Trial Protocols. BMJ 2026;392:e085062. doi: 10.1136/bmj-2025-085062

Explanation and Elaboration: Baba A, Smith M, Potter BK, et al. SPIRIT-C 2026 explanation and elaboration: recommendations for enhancing the reporting and impact of paediatric randomised trials. BMJ 2026;392:e085064. doi: 10.1136/bmj-2025-085064