

CONSORT 2010 Checklist

Title and abstract

1a. Identification as a randomized trial in the title

Location: Title and Abstract

1b. Structured abstract: background, methods, results, conclusions

Location: Abstract

Introduction

2a. Scientific background and explanation of rationale

Location: Introduction, paragraphs 1–4

2b. Specific objectives or hypotheses

Location: Abstract (Objectives); Introduction, final paragraph

Methods: Participants

3a. Eligibility criteria for participants

Location: Materials and Methods, Study subjects, Inclusion and exclusion criteria

3b. Settings and locations where the data were collected

Location: Materials and Methods, Study subjects (single-center, Wenzhou People's Hospital, China)

Methods: Interventions

4a. Precise details of the interventions intended for each group

Location: Materials and Methods, Surgical procedure standards, Placement method

4b. How and when interventions were administered

Location: Materials and Methods, Timing of surgery and anesthesia; Placement method

Methods: Outcomes

5a. Clearly defined primary and secondary outcome measures

Location: Materials and Methods, Primary and secondary end points

5b. Any changes to trial outcomes after the trial commenced

Location: N/A

Methods: Sample size

6a. How sample size was determined

Location: Materials and Methods, Study subjects (sample size calculation)

6b. Interim analyses and stopping rules

Location: N/A

Methods: Randomization

7a. Method of random sequence generation

Location: Materials and Methods, Randomization and allocation concealment (computer-generated random number sequence)

7b. Allocation concealment mechanism

Location: Materials and Methods, Randomization and allocation concealment (sealed opaque envelopes)

7c. Implementation: who generated sequence, who enrolled, who assigned

Location: Materials and Methods, Randomization and allocation concealment (independent researcher, study nurse)

Methods: Blinding

8a. Who was blinded after assignment to interventions

Location: Materials and Methods, Randomization and allocation concealment (outcome assessors and statisticians blinded; patients and operators unblinded)

8b. If blinded, how blinding was maintained

Location: Materials and Methods, Randomization and allocation concealment

8c. If not blinded, explain why

Location: Materials and Methods, Randomization and allocation concealment (different device configurations and implantation procedures)

Methods: Statistical methods

9a. Statistical methods for comparing groups on primary and secondary outcomes

Location: Materials and Methods, Statistical methods (χ^2 test, one-way ANOVA, t-test, Kaplan–Meier method, log-rank test)

9b. Methods for additional analyses (subgroup, adjusted)

Location: Materials and Methods, Statistical methods (subgroup analysis by uterine cavity depth); Results, Subgroup analysis

Results: Participant flow

10a. Flow diagram showing numbers at each stage

Location: Figure 1 (Study flow chart)

10b. Losses and exclusions after randomization, with reasons

Location: Results, Patient baseline data (31 patients lost to follow-up)

Results: Recruitment

11a. Dates defining recruitment and follow-up periods

Location: Materials and Methods, Postoperative management and follow-up plan (1, 3, and 6 months post-implantation)

11b. Trial registration number and name of trial registry

Location: N/A

Results: Baseline data

12a. Baseline characteristics of each group

Location: Table 1 (Baseline data comparison)

Results: Numbers analyzed

13a. Number randomized, analyzed in each group

Location: Results, Patient baseline data (n=90 per group); Results sections (n=82/79/78 for follow-up analyses)

Results: Outcomes and estimation

14a. For each primary and secondary outcome, results with effect size and precision

Location: Results, Primary endpoints; Results, Secondary endpoints; Table 2; Table 3

14b. Absolute and relative effect sizes

Location: Results, Primary endpoints (displacement/expulsion rates, χ^2 and *P* values)

Results: Ancillary analyses

15a. Multiple analyses performed (adjusted, subgroup)

Location: Results, Subgroup analysis; Table 4

Results: Harms

16a. All important adverse events or side effects in each group

Location: Results, Comparison of adverse reaction incidence rates

Discussion

17a. Limitations of the trial, addressing sources of bias, imprecision, multiplicity

Location: Discussion, Study limitations

17b. Generalizability (external validity) of the trial findings

Location: Discussion, Study limitations

17c. Interpretation consistent with results, balancing benefits and harms

Location: Discussion; Conclusion

Other information

18a. Trial registration number

Location: N/A

18b. Protocol availability

Location: N/A

18c. Funding and support sources

Location: Funding (Wenzhou Basic Public Welfare Scientific Research Project, No. Y2023522)