Supplementary Table 1. CONSORT checklist

|  |  |  |  |
| --- | --- | --- | --- |
| **Section/Topic** | **Item no.** | **Checklist item** | **Reported on**Page/Section/Paragraphs(s) |
| Title and abstract |
|  | 1a | Identification as a randomized trial in the title | P1/Line 1 |
| 1b | Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts) | P1-2/Abstract |
| Introduction |
| Background and objectives | 2a | Scientific background and explanation of rationale | P3 |
| 2b | Specific objectives or hypotheses | P3-4/Intro/Last para |
| Methods |
| Trial design | 3a | Description of trial design (such as parallel, factorial) including allocation ratio | P4/Participants and study Design/first para |
| 3b | Important changes to methods after trial commencement (such as eligibility criteria), with reasons | NA |
| Participants | 4a | Eligibility criteria for participants | P4/Participants and study Design/first para |
| 4b | Settings and locations where the data were collected | P4/Participants and study Design/first para |
| Interventions | 5 | The interventions for each group with sufficient details to allow replication, including how and when they were actually administered | P4-5/Participants and study Design, and Procedures |
| Outcomes | 6a | Completely defined prespecified primary and secondary outcome measures, including how and when they were assessed | P5-6/Outcomes and Resistance analyses |
| 6b | Any changes to trial outcomes after the trial commenced, with reasons | NA |
| Sample size | 7a | How sample size was determined | P7/Statistical analysis |
| 7b | When applicable, explanation of any interim analyses and stopping guidelines | NA |
| Randomization |
| Sequence generation | 8a | Method used to generate the random allocation sequence | NA (previously described) |
| 8b | Type of randomization; details of any restriction (such as blocking and block size) | NA (previously described) |
| 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 | NA (previously described) |
| Implementation | 10 | Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions | NA (previously described) |
| Blinding | 11a | If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how | P4/Participants and study design |
| 11b | If relevant, description of the similarity of interventions | NA |
| Statistical methods | 12a | Statistical methods used to compare groups for primary and secondary outcomes | P7/Statistical analyses |
| 12b | Methods for additional analyses, such as subgroup analyses and adjusted analyses | NA |
| 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 analyzed for the primary outcome | P7-8/Participant disposition and baseline characteristics  |
| 13b | For each group, losses and exclusions after randomization, together with reasons | P7-8/Participant disposition and baseline characteristics  |
| Recruitment | 14a | Dates defining the periods of recruitment and follow-up | P7-8/Participant disposition and baseline characteristics  |
| 14b | Why the trial ended or was stopped | NA |
| Baseline data | 15 | A table showing baseline demographic and clinical characteristics for each group | P7-8/Participant disposition and baseline characteristics  |
| Numbers analyzed | 16 | For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups | P7/Participant disposition and baseline characteristics  |
| 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) | P8-12 |
| 17b | For binary outcomes, presentation of both absolute and relative effect sizes is recommended | P8-12 |
| Ancillary analyses | 18 | Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing prespecified from exploratory | NA |
| Harms | 19 | All important harms or unintended effects in each group (for specific guidance see CONSORT for harms) | P10-12/Safety |
| Discussion |
| Limitations | 20 | Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses | P16/Lines 355-364 |
| Generalizability | 21 | Generalizability (external validity, applicability) of the trial findings | P16/Lines 355-357 |
| Interpretation | 22 | Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence | P12-16 |
| Other information |
| Registration | 23 | Registration number and name of trial registry | P2/Trial registration |
| Protocol | 24 | Where the full trial protocol can be accessed, if available | NA |
| Funding | 25 | Sources of funding and other support (such as supply of drugs), role of funders | Provided in the Title Page under Funding |