| Section/item            | Item No | Description                                                                 | Reported on Page Number/Line Number | Reported on Section/Paragraph |
|-------------------------|---------|------------------------------------------------------------------------------|-------------------------------------|------------------------------|
| Administrative information |         |                                                                              |                                     |                              |
| Title                   | 1       | Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym | page 4 line 54-55 & page 4-1       | Trial registration &         |
| Trial registration      | 2a      | Trial identifier and registry name. If not yet registered, name of intended registry | page 3-4 line 51-55                | Trial registration           |
|                         | 2b      | All items from the World Health Organization Trial Registration Data Set       | page 3-4 line 51-55                | Trial registration           |
| Protocol version        | 3       | Date and version identifier                                                  | page 11 line 213-214               | Funding, registration and    |
| Funding                 | 4       | Sources and types of financial, material, and other support                  | page 11 line 209-211               | Funding, registration and    |
| Roles and responsibilities | 5a     | Names, affiliations, and roles of protocol contributors                      | page 15 line 281-289               | Authors contribution        |
|                         | 5b      | Name and contact information for the trial sponsor                           | page 11 line 209-211               | Funding, registration and    |
|                         | 5c      | Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities | page 11 line 209-211               | Funding, registration and current status |
|                         | 5d      | Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee) | page 11 line 198-203               | Monitoring                   |
| Introduction            |         |                                                                              |                                     |                              |
| Background and rationale | 6a      | Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention | page 5 line 59-82                 | Background                   |
|                         | 6b      | Explanation for choice of comparators                                         | page 5 line 78-82                 | Background                   |
| Objectives              | 7       | Specific objectives or hypotheses                                             | page 5 line 78-80                 | Background                   |
| Trial design | 8 | Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory) | page 5-6 line 91-97 | Methods and design |
|---|---|---|---|---|
| **Methods: Participants, interventions, and outcomes** | | | | |
| Study setting | 9 | Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained | page 5-6 line 91-97 | Methods and design |
| Eligibility criteria | 10 | Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists) | page 6-9 line 113-171 | Participants |
| Interventions | 11a | Interventions for each group with sufficient detail to allow replication, including how and when they will be administered | page 9-10 line 164-182 | Methods and design |
| | 11b | Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease) | page 11 line 197-203 | Monitoring |
| | 11c | Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests) | N/A | That strategies was not designed. |
| | 11d | Relevant concomitant care and interventions that are permitted or prohibited during the trial | N/A | That was not designed. |
| Outcomes | 12 | Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended | page 6 line 99-112 | Study endpoint |
| Participant timeline | 13 | Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure) | page 10 line 179-188 | Methods and design |
| Sample size | 14 | Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations | page 11 line 194-195 | Statistical analysis |
| Recruitment | 15 | Strategies for achieving adequate participant enrolment to reach target sample size | N/A | That strategies was not |
| **Methods: Assignment of interventions (for controlled trials)** | | | | |
| Allocation: | | | | |
| Sequence generation | 16a | Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions | page 9 line 166-171 | Masking and randomization |
| Allocation concealment mechanism | 16b | Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned | page 9 line 161-171 | Masking and randomization |
| Implementation 16c | Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions | page 7 line 120-124 | Participants |
| Blinding (masking) 17a | Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how | N/A | This study is unmasked |
| 17b | If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant’s allocated intervention during the trial | N/A | This study is unmasked |

**Methods: Data collection, management, and analysis**

| Data collection methods 18a | Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol | N/A | It was not open. You could only get it from PI. |
| 18b | Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols | N/A | no plan |

| Data management 19 | Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol | page 9 line 164-171 | Masking and randomization |

| Statistical methods 20a | Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol | page 11 line 189-196 & page 6 line 99-111 | Statistical analysis & study endpoint |
| 20b | Methods for any additional analyses (eg, subgroup and adjusted analyses) | N/A | no additional analyses |
| 20c | Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation) | page 11 line 189-196 | Statistical analysis |

**Methods: Monitoring**

| Data monitoring 21a | Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed | page 11 line 197-203 | Monitoring |
| 21b | Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial | N/A | no interim analyses plan |

| Harms 22 | Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct | page 11 line 197-203 | Monitoring |

| Auditing 23 | Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor | page 11 line 197-203 | Monitoring |
| Ethics and dissemination                                      | page 5 line 85-89 | Statement of ethics approval |
|--------------------------------------------------------------|--------------------|-----------------------------|
| Research ethics approval                                     | page 7 line 123-124| Participants                |
| Protocol amendments                                          | N/A                | no plan                     |
| Consent or assent                                            | N/A                | No sample collection. No additional consent |
| Confidentiality                                              | page 11 line 197-203| Monitoring                   |
| Declaration of interests                                     | page 11 line 204-211| Participating institutions & Funding, registration and |
| Access to data                                               | page 11 line 201-203| Monitoring                   |
| Ancillary and post-trial care                                | N/A                | no plan                     |
| Dissemination policy                                         | The main sponsor is Henan Cancer Hospital. TopAlliance has no access of any results. Raw data |
| Appendices                                                   | page 7 line 123-124| Participants                |
| Informed consent materials                                   | N/A                | no plan                     |
| Biological specimens                                         | N/A                | no plan for collect samples |

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons “Attribution-NonCommercial-NoDerivs 3.0 Unported” license.

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*As the checklist was provided upon initial submission, the page number/line number reported may be changed due to copyediting and may not be referable in the published version. In this case, the section/paragraph may be used as an alternative reference.