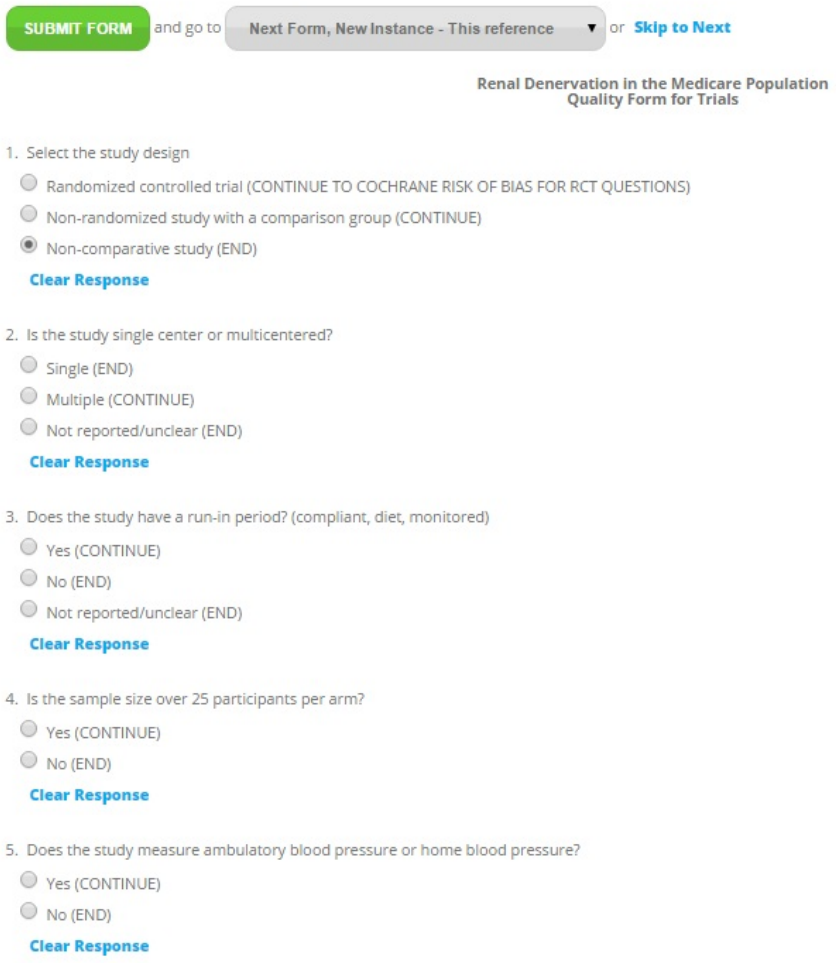
Data Abstraction – Quality Form



SUBMIT FORM and go to Next Form, New Instance - This reference or Skip to Next

Renal Denervation in the Medicare Population
Quality Form for Trials

1. Select the study design
   - ○ Randomized controlled trial (CONTINUE TO COCHRANE RISK OF BIAS FOR RCT QUESTIONS)
   - ○ Non-randomized study with a comparison group (CONTINUE)
   - ◉ Non-comparative study (END)

   Clear Response

2. Is the study single center or multicentered?
   - ○ Single (END)
   - ○ Multiple (CONTINUE)
   - ○ Not reported/unclear (END)

   Clear Response

3. Does the study have a run-in period? (compliant, diet, monitored)
   - ○ Yes (CONTINUE)
   - ○ No (END)
   - ○ Not reported/unclear (END)

   Clear Response

4. Is the sample size over 25 participants per arm?
   - ○ Yes (CONTINUE)
   - ○ No (END)

   Clear Response

5. Does the study measure ambulatory blood pressure or home blood pressure?
   - ○ Yes (CONTINUE)
   - ○ No (END)

   Clear Response

The Cochrane Collaboration's tool for assessing risk of bias

Sequence Generation

Was the allocation sequence adequately generated? Select an Answer

Criteria for a judgment of "YES" (i.e., low risk of bias)
The investigators describe a random component in the sequence generation process such as:
Referring to a random number table; Using a computer random number generator; Coin tossing; Shuffling cards or envelopes; Throwing dice; Drawing of lots; Minimization. Minimization may be implemented without a random element, and this is considered to be equivalent to being random.
Criteria for a judgment of "NO" (i.e., high risk of bias)
The investigators describe a non-random component in the sequence generation process. Usually, the description would involve some systematic, non-random approach, for example:
Sequence generated by odd or even date of birth;
Sequence generated by some rule based on date (or day) of admission;
Sequence generated by some rule based on hospital or clinic record number.
Other non-random approached happen much less frequently than the systematic approaches mentioned above and tend to be obvious. They usually involve judgment or some method of non-random categorization of participants, for example:
Allocation by judgment of the clinician;
Allocation by preference of the participant;
Allocation based on the results of a laboratory test or a series of tests.
Criteria for a judgment of "UNCLEAR" (i.e., uncertain risk of bias)
Insufficient information about the sequence generation process to permit judgement of "YES" or "NO."

Allocation Concealment

Was allocation adequately concealed? Select an Answer

Criteria for a judgment of "YES" (i.e. low risk of bias)
Participants and investigators enrolling participants could not foresee assignment because one of the following, or an equivalent method, was used to conceal allocation:
Central allocation (including telephone, web-based, and pharmacy-controlled, randomization);
Sequentially numbered drug containers of identical appearance;
Sequentially numbered, opaque, sealed envelopes.
Criteria for a judgment of "NO" (i.e. high risk of bias)
Participants or investigators enrolling participants could possibly foresee assignments and thus introduce selection bias, such as allocation based on:
Using an open random allocation schedule (e.g. a list of random numbers);
Assignment envelopes were used without appropriate safeguards (e.g. if envelopes were unsealed or non-opaque or not sequentially numbered);
Alternation or rotation;
Date of birth;
Case record number;
Any other explicitly unconcealed procedure
Criteria for the judgment of "UNCLEAR" (i.e. uncertain risk of bias)
Insufficient information about the sequence generation process to permit judgment of "YES" or "NO".
This is usually the case if the method of concealment is not described or not described in sufficient detail to allow a definite judgment – for example if the use of assignment envelopes is described, but it remains unclear whether envelopes were sequentially numbered, opaque and sealed.

Blinding of Participants, Personnel, and Outcome Assessors

Was knowledge of the allocated interventions adequately prevented during the study? Select an Answer

Criteria for a judgment of "YES" (i.e. low risk of bias)
Any one of the following:
No blinding, but the review authors judge that the outcome and the outcome
Blinding of participants and key study personnel ensured, and unlikely that the blinding could have been broken;
Either participants or some key study personnel were not blinded, but outcome assessment was blinded and the nonblinding of others unlikely to introduce bias.
Criteria for a judgment of "NO" (i.e. high risk of bias)
Any one of the following:
No blinding or incomplete blinding, and the outcome or outcome measurement is likely to be influenced by lack of blinding;
Blinding of key study participants and personnel attempted, but likely that the blinding could have been broken;
Either participants or some key study personnel were not blinded, and the non-blinding of others likely to introduce bias.
Criteria for the judgment of "UNCLEAR" (i.e. uncertain risk of bias)
Any one of the following:
Insufficient information to permit judgment of 'Yes' or 'No';
The study did not address this outcome.

Incomplete Outcome Data

Select an Answer

Were incomplete outcome data adequately addressed?

Criteria for a judgment of "YES" (i.e. low risk of bias)
Any one of the following:
No missing outcome data;
Reasons for missing outcome data unlikely to be related to true outcome (for survival data, censoring unlikely to be introducing bias);
Missing outcome data balanced in numbers across intervention groups, with similar reasons for missing data across groups;
For dichotomous outcome data, the proportion of missing outcomes compared with observed event risk not enough to have a clinically relevant impact on the intervention effect estimate;
For continuous outcome data, plausible effect size (difference in means or standardized difference in means) among missing outcomes not enough to have a clinically relevant impact on observed effect size;
Missing data have been imputed using appropriate methods.
Criteria for a judgment of "NO" (i.e. high risk of bias)
Any one of the following:
Reason for missing outcome data likely to be related to true outcome, with either imbalance in numbers or reasons for missing data across intervention groups;
For dichotomous outcome data, the proportion of missing outcomes compared with observed event risk enough to induce clinically relevant bias in intervention effect estimate;
For continuous outcome data, plausible effect size (difference in means or standardized difference in means) among missing outcomes enough to induce clinically relevant bias in observed effect size;
'As-treated' analysis done with substantial departure of the intervention received from that assigned at randomization;
Potentially inappropriate application of simple imputation
Criteria for the judgment of "UNCLEAR" (i.e. uncertain risk of bias)
Any one of the following:
Insufficient reporting of attrition/exclusions to permit judgment of 'Yes' or 'No' (e.g. number randomized not stated, no reasons for missing data provided);
The study did not address this outcome.

Selective Outcome Reporting

Are reports of the study free of suggestion of selective reporting?

Select an Answer ▼

Criteria for a judgement of "YES" (i.e. low risk of bias)
Any of the following:
The study protocol is available and all of the study's pre-specified (primary and secondary) outcomes that are of interest in the review have been reported in the pre-specified way;
The study protocol is not available but it is clear that the published reports include all expected outcomes, including those that were pre-specified (convincing text of this nature may be uncommon).
Criteria for a judgement of "NO" (i.e. high risk of bias)
Any one of the following:
Not all of the study'es pre-specified primary outcomes have been reported;
One or more primary outcomes is reported using measurements, analysis methods or subsets of the data (e.g., subscales) that were not pre-specified;
One or more reported primary outcomes were not pre-specified (unless clear jusitification for their reporting is provided, such as an unexpected adverse effect);
One or more outcomes of interest in the review are reported incompletely so that they cannot be entered in a meta-analysis;
The study report fails to include results for a key outcome that would be expected to have been reported for such a study.
Criteria for the judgement of "UNCLEAR" (i.e. uncertain risk of bias)
Insufficient information to permit judgement of "Yes" or "No". It is likely that the majority of studies will fall into this category.

Other sources of bias

Was the study apparently free of other problems that could put it at a high risk of bias? Select an Answer ▼

Criteria for a judgement of "YES" (i.e. low risk of bias)
The study appears to be free of other sources of bias
Criteria for a judgement of "NO" (i.e. high risk of bias)
There is at least one important risk of bias. For example, the study:
Had a potential source of bias related to the specific study design used; or
Stopped early due to some data-dependent process (including a formal-stopping rule); or
Had extreme baseline imbalance; or
Has been claimed to have been fraudulent; or
Had some other problem.
Criteria for the judgement of "UNCLEAR" (i.e. uncertain risk of bias)
There may be a risk of bias, but there is either:
Insufficient information to assess whether an important risk of bias exists; or
Insufficient rationale or evidence that an identified problem will introduce bias.

Downs and Black Quality Form

12. Have all important adverse events that may be a consequence of the intervention been reported?

- Yes
- No

Clear Response

13. Was compliance with the intervention/s reliable?

- Yes
- No
- Unable to determine

Clear Response

14. Were the main outcome measures used accurate (valid and reliable)?

- Yes
- No
- Unable to determine

Clear Response

15. Was the randomised internvetion assignment concealed from both patients and health care staff until recruitment was complete and irrevocable?

- Yes
- No
- Unable to determine

Clear Response

16. Was there adequate for confounding in the analyses from which the main findings were drawn?

- Yes
- No
- Unable to determine

Clear Response

SUBMIT FORM and go to Next Form, New Instance - This reference or Skip to Next