# A systematic review of clinical trials of homeopathy in urological disorders

*Chaturbhuja Nayak, Rajkumar Manchanda, Deepti Singh, Jürgen Paneek, Abhijit Chattopadhyay, Munmun Koley, Subhranil Saha*

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## Review question

The aim of the planned analysis is to systematically review the homeopathic clinical trials on urological disorders to evaluate whether homeopathy treatment (alone or as additive to standard therapy) could produce any significant treatment effect.

## Searches

MEDLINE (via PubMed), EMBASE (Elsevier), Cochrane Central Register of Controlled Trials (CENTRAL) (Wiley interface), CORE-Hom (Carl and Veronica Carstens-Stiftung), ChiroACCESS (MANTIS interface), LILACS (Biblioteca virtual em salud interface), Trial registries (CTRI, ClinicalTrials.gov, etc.), DOAJ, Web of Science, and Google Scholar will be used for the literature search along with manual search in relevant journals, magazines etc. Language: Any. Publication period: Jan 1, 1981 to Dec 31, 2016.

## Types of study to be included

Any type of clinical trial – randomised, non-randomised, controlled, non-controlled, observational etc, published between 1981 and 2016 will be considered. Qualitative studies, repeat publications and translations, and papers dealing with theoretical/methodological aspects, and papers not reporting any experimental results will be excluded.

## Condition or domain being studied

Urological disorders.

## Participants/population

Patients suffering from urological disorders.

## Intervention(s), exposure(s)

Homeopathic treatment.

## Comparator(s)/control

Placebo and/or conventional therapies and/or others or none.

## Primary outcome(s)

Treatment effects of homeopathic medicines with that of placebo or standard therapies.

*Timing and effect measures*

Effect sizes will be measured in terms of standardised mean differences and OR as reported over different time points.

## Secondary outcome(s)

Not applicable.

## Data extraction (selection and coding)

Data extraction will be performed utilizing standardized Microsoft Excel files. Two reviewers will extract the data and will double-check the information independently. The following data will be extracted from the included studies: 1. Publication type (substantive research article peer-reviewed; substantive research article non peer-reviewed; minor research article peer-reviewed; thesis; minor research article non peer-reviewed;

master thesis; doctoral thesis; conference proceedings) 2. Study aim and target population 3. Inclusion and exclusion criteria 4. Study design (RCT, controlled cohort study, case-controlled study, etc.) 5. Intervention details (potency; type of homeopathy (individualized / classical; clinical; complex; isopathic; preventive) 6. Control details: placebo or conventional treatment as control or none; homeopathy as additive or not 7. Number of patients that have participated, and that have been evaluated in each group; attrition rate; intention-to-treat or per-protocol analysis 8. Statistical reporting: Statistical values: measures of central tendency and dispersion for continuous data, number of favorable events for dichotomous data, etc. 9. External and internal validity indicators 10. Funding and declared conflicts of interest.

## Risk of bias (quality) assessment

Three reviewers will independently assess the risk of bias in included studies. Disagreements on data extraction will be resolved by discussion. If information should be missing, the study authors will be contacted by e-mail. The internal validity of the RCTs will be evaluated by the Cochrane Collaboration's tool for assessing the risk of bias in randomised trials for the seven following domains: (1) random sequence generation (2) allocation concealment (3) blinding of participants and personnel (4) blinding of outcome assessment (5) incomplete outcome data (6) selective reporting (7) anything else. The internal validity of the observational studies will be assessed by the Cochrane risk of bias assessment tool for non-randomised studies of interventions for the seven following bias domains: (1) confounding (2) selection of participants into the study (3) measurement of interventions (4) departures from intended interventions (5) missing data (6) measurement of outcomes (7) selection of reported results. The homeopathic model validity will be evaluated by the six judgemental domains proposed by Mathie RT, et al, 2015: (1) rationale for the choice of the particular homeopathic intervention (2) homeopathic principles reflected in the intervention (3) extent of homeopathic practitioner input (4) nature of the main outcome measure (5) capability of the main outcome measure to detect change (6) length of the follow-up to the endpoint of the study The quality of homeopathic individualisation will be evaluated by the six judgemental domains proposed by Saha S, et al, 2014: (1) Single medicine prescription when required on each occasion (2) Medicine individualisation (3) Proper description of approach to medicine individualisation (4) Dose individualisation (5) Proper description of approach to dose individualisation (6) Subsequent prescriptions as per Kent's observations and/or Hering's law. However, assessment of quality will not influence the planned synthesis due to the exploratory character of the review.

## Strategy for data synthesis

We will provide a narrative synthesis of the findings from the included studies, structured around outcome and intervention / comparator. No quantitative meta-analysis has so far been planned comparing treatment effects of homeopathic medicines with that of placebo or standard therapies.

Primary strategy for data synthesis will be Odds ratio (OR). From dichotomous data, OR will be calculated. If the outcomes are reported as continuous, we will calculate effect sizes in terms of standardised mean difference (SMD) and that will be subsequently transformed to OR. For inadequately reported data, we shall try to recover the data by contacting the authors; otherwise will describe the outcome as "not estimable".

As we expect considerable variety in outcomes, those will be considered as reported in all data formats (e.g., dichotomous, continuous); and will be finally converted into OR.

## Analysis of subgroups or subsets

None planned.

## Contact details for further information

Subhranil Saha
drsubhranilsaha@hotmail.com

## Organisational affiliation of the review
Homoeopathy University, Jaipur, India
https://www.homoeopathyuniversity.org/

## Review team members and their organisational affiliations
Dr Chaturbhuja Nayak. President, Homoeopathy University, Jaipur, India
Dr Rajkumar Manchanda. Director General, Central Council for Research in Homoeopathy, India
Dr Deepti Singh. Scientist-1, Central Council for Research in Homoeopathy, India
Dr Jürgen Paneek. Dept. of Neuro-Urology, Swiss Paraplegic Centre, Nottwil, Switzerland
Dr Abhijit Chattopadhyay. National Institute of Homoeopathy, India
Dr Munmun Koley. Assistant Editor, IJRH, Central Council for Research in Homoeopathy, India
Dr Subhranil Saha. Postgraduate Trainee, National Institute of Homoeopathy, India

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01 March 2018

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None

## Conflicts of interest

## Language
English

## Country
India

## Stage of review
Review_Ongoing

## Subject index terms status
Subject indexing assigned by CRD

## Subject index terms
Homeopathy; Humans; Research Design; Urologic Diseases

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26 January 2018

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## Details of any existing review of the same topic by the same authors

## Stage of review at time of this submission

| Stage | Started | Completed |
|---|---|---|
| Preliminary searches | Yes | No |
| Piloting of the study selection process | No | No |
| Formal screening of search results against eligibility criteria | No | No |
| Data extraction | No | No |
| Risk of bias (quality) assessment | No | No |
| Data analysis | No | No |

## Versions

26 January 2018