Reviewer's report

**Title:** Auricular acupuncture for prehypertension and stage 1 hypertension: study protocol for a pilot multicentre randomised controlled trial

**Version:** 2 **Date:** 28 November 2012

**Reviewer:** François Gueyffier

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The planned trial is ongoing, registered on the WHO trial registry. It is an open-label parallel groups trial, comparing auricular acupuncture to usual care in patients with pre- or mild hypertension. The mean measurements of systolic and diastolic blood pressure from ambulatory blood pressure exam will be used as main outcomes, with several other secondary outcomes e.g. regarding blood pressure variability.

The average of 3 measurements will be used to define hypertension and pre-hypertension: will these measures be consecutive? in which circumstances will they been recorded?

The randomization is stratified on age and sex: how many classes of age are planned for it?

The trial size is not statistically justified, the trial aiming at supporting the computation of the size of the future full scale trial. Why not basing the sample size on previous already available studies in the field?

The main rationale for this trial is to reduce the uncertainty of previous trials, attributed to poor methodology. Why not using sham control? This would allow better distribution of placebo effect between two groups.

The discussion should address the clinical relevance of blood pressure lowering as an outcome. Would the demonstration that acupuncture decrease blood pressure be sufficient to make it recommended?

**Level of interest:** An article of limited interest

**Quality of written English:** Acceptable

**Statistical review:** No, the manuscript does not need to be seen by a statistician.

**Declaration of competing interests:**

I conduct a trial with limited support from pharmaceutical industry (free delivery of drugs, and realisation of drug dosages), and a grant for French Ministery of Health. I have performed several systematic reviews on the effects of blood pressure lowering drugs.