Author's response to reviews

Title: Randomised controlled trial of cervical radiofrequency lesions as a treatment for cervicogenic headache [ISRCTN 07444684]

Authors:
Sarah RS Haspeslagh (shas@anaesth.azm.nl)
Hans A van Suijlekom (j.a.van.suijlekom@freeler.nl)
Inge E Lame (iel@sane.azm.nl)
Alfons HF Kessels (akes@kemta.azm.nl)
Maarten van Kleef (mvk@sane.azm.nl)
Wim EJ Weber (wweb@neurologie.azm.nl)

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Author's response to reviews:

Please find our revised manuscript.

We appreciate the meticulous way with which the reviewers have read our manuscript and we have revised it accordingly.

Reviewer 1 (Prof. L.J. Stovner):

1. Degree of blinding: We have included on p.7, line 8 the following text: This investigator (IEL) did not take part in the actual treatment process and was thus not aware of the treatment that the patient had received. Patients were aware of this and were asked not to mention their received therapy. As we did not check the blinding efficacy, we cannot rule out that some unblinding of the invetsigator actually took place. We were under the impression that IEL remained blinded for treatment allocation throughout the trial. We included in the discussion (p.14, line 11) the following remark: Because of the lack of difference between the two treatment groups, we feel that the blinding of the evaluating investigator in the present study was relatively good, as one would expect a possible bias to emerge preferably in the more invasively treated group.

2. Prof. Stovner is correct. We apologise for this mistake and we have corrected this. We inserted the following sentence on p.4, line 8: We discussed the trial design extensively with colleagues of the department of Neurology, Trondheim University Hospital, Norway, ....

3. There is no point (5) in the selection criteria on p.4, but prof. Stovner is probably referring to (4), which is, admittedly, a repitition of the criteria for Cervicogenic Headache. We have omitted (4).

4. We have included on p.7, line 13: We obtained these ratings from the diary that the patients kept throughout the trial. Duration of baseline level assessment was 4 weeks and was added to p.7, line 27.

5. A VAS reduction of 20 mm is meant, is now corrected on p.7, line 18.

6. We apologise for this very careless mistake. The number is per 4 weeks and not per week.

7. We have corrected Table 3 accordingly

8. The IRB is indeed the Research Ethics Committee. We included this is the text on p.4, line 5.

Reviewer 2 : R.R.W. Evans

We thank dr Evans for his compliments and acknowledge the need for a placebo group. We omitted this for both ethical and practical reasons (it is nearly impossible to have chronic severe headache patients forgoing every treatment for 6 months...
As requested we now included a discussion (with the suggested literature references) on diagnostic criteria for CEH on p.14, line 4:

Although CEH is a controversial diagnosis[1], it is a widely used diagnosis for which radiofrequency treatment is given in routine clinical care. As the scientific basis for this therapy is also controversial, we sought to restrict ourselves to a clearly defined headache syndrome. We demonstrated earlier that CEH can be relatively reliably delineated from the other primary headaches[2]. We feel that the rigorous selection of patients such as we did for this trial (see below) led to a rather homogenous group of CEH patients. These patients, with a strictly unilateral headache without side-shift and pain originating in the neck, were shown by Antonaci et al[3]to be most reliably diagnosable as CEH. Most of these would probably also fulfill the International Headache Classification criteria for CEH[4].