Author's response to reviews

Title: Assessment of the Feasibility of High-Concentration Capsaicin Patches in the Pain Unit of a Tertiary Hospital for a Population of Mixed Refractory Peripheral Neuropathic Pain Syndromes in Non-Diabetic Patients

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According to the criteria of the International Committee of Medical Journal editors (http://www.icmje.org/faq_clinical.html), we would consider your study to constitute a clinical trial. We must therefore again request that you include a trial registration number in your manuscript. It should be entirely possible to obtain this retrospectively. Please note that we only accept registration numbers issued by registries that meet all of the ICMJE criteria (http://www.icmje.org/publishing_10register.html). Registries which meet the requirements of the ICMJE include WHO Primary Registries (http://www.who.int/ictrp/network/primary/en/index.html).

A: Albeit that the WHO’s definition of clinical trial is “any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes”, the protocol of this study was planned as observational study. The design of our study was “Observational Prospective Single-Center Study (cohort study)” based on clinical practice. That is, the assignment of the medical intervention was not at the discretion of the investigator.

Therefore, given that this study is an observational study, and according to the criteria of the International Committee of Medical Journal editors about observational studies (“purely observational studies (those in which the assignment of the medical intervention is not at the discretion of the investigator) will not require registration”), the trial registration number was not obtained.

On the other hand, in order to avoid misunderstanding, the terminology of clinical trials has been avoided along the manuscript.

With regards to the patient consent associated with your study, we are satisfied that each patient provided consent to participate. However, we require a specific statement detailing that consent to publish identifiable personal information, such as that featured in your tables, was obtained from each patient.

A: We have checked the information along the manuscript, and specifically from the tables 1 and 2, and identifiable personal information is not provided. Moreover, this study fulfilled with the Spanish law (LOPD 15/1999) concerning the protection of personal data. After consulting our expert lawyers on this issue, the information facilitated in the tables (sex, age, diagnostic, questionnaires) are not considered enough to identify ‘easily’ to our patients.

In the original manuscript this point was provided “concerning the protection of personal data as required by Spanish laws (LOPD 15/1999) was ensured”. But, to give more clarity on this issue, the following sentence has been re-written in the new version of the manuscript: “This study was performed according to the stipulations of the Declaration of Helsinki and the level of protection of confidentiality concerning the protection of personal data as required by Spanish laws (LOPD 15/1999) was ensured. All patients gave their written informed consent for their medical information to be used for purposes of scientific research in accordance with the ethical committee of the participating site. The Ethical Committee approved the informed consent in September 2010.”