Author's response to reviews

Title: Subanesthetic ketamine for the treatment of children and adolescents with chronic pain: an outpatient longitudinal study

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Version: 2  Date: 7 April 2015

Author's response to reviews:

Response to required revisions prior to editorial assignment

Editor's comment:

"We note that it is mentioned within the paper that a waiver for informed consent was obtained. For such studies we would normally require written informed consent from the patients, and where patient is a minor the written informed consent would need to be from a parent/guardian. Please confirm if the appropriate consent was obtained for this study. Please clarify whether the treatments/ drugs administered in this study was part of normal standard care.

Response- We indicate in the methods that “This study was performed in compliance with the Helsinki Declaration. The study protocol was approved by the Children’s National Health System Institutional Review Board. A waiver of informed consent for this study was also approved by the Children’s National Health System Institutional Review Board, as the data examined had been collected during the clinical care of the patients and was de-identified after its collection. Consent was obtained as part of clinical care for administration of ketamine.

Please include information regarding the age range of the patients involved in this study.

Response: The age range is now indicated in the abstract, results, and Table 2

For further information regarding the journal requirements and policy, please visit the following link:
http://www.biomedcentral.com/bmcpediatr/authors/instructions/researcharticle"

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Additional formatting request:
1. Line Numbering:

Please revise your manuscript to include line and page numbers. Authors are asked to ensure that line numbering is included in the main text file of their manuscript at the time of submission to facilitate peer-review. Once a manuscript has been accepted, line numbering should be removed from the manuscript before publication. For authors submitting their manuscript in Microsoft Word please do not insert page breaks in your manuscript to ensure page numbering is consistent between your text file and the PDF generated from your submission and used in the review process.

Response: Line numbers were inserted

2. Trial Registration Number:

We notice that you are reporting a clinical trial but have not cited a trial registration number. This must be obtained before we can begin peer review of your manuscript.

BioMed Central has always supported initiatives to improve the performance and reporting of clinical trials, part of which includes prospective registering and numbering of trials. BioMed Central requests a trial registration number for manuscripts reporting work that falls within the International Committee of Medical Journal Editors (ICMJE) definition of a clinical trial: any research study that prospectively assigns human subjects to one or more health related interventions to evaluate the effects on health outcomes.

We would like you to confirm that your clinical trial is in a publicly accessible registry before we begin peer review. The trial registration number should be included as the last line of the abstract of the manuscript.

Please note that we only accept registration numbers issued by registries that meet all of the ICMJE criteria (http://www.icmje.org/about-icmje/faqs/clinical-trials-registration/ ). Registries which meet the requirements of the ICMJE include WHO Primary Registries (http://www.who.int/ictrp/network/primary/en/index.html).

Once you know your trial registration number, please submit a revised version of your manuscript with the number included in the abstract. The last section of the abstract should be Trial Registration: listing the trial registry and the unique identifying number and the date of registration, e.g. Trial registration: Current Controlled Trials ISRCTN73824458. Registered 28 September 2004. Please note that there should be no space between the letters and numbers of the trial registration number.

If you have applied to register your trial but are experiencing delays please provide us with the details of your registration.

Response: We regret this confusion. This study is not a clinical trial, rather it is a longitudinal study that examines the effect of administration of intravenous
subanesthetic dose of ketamine in pain intensity and opioid intake. The data examined was collected as part of the patient’s clinical care and it does not include a control arm. For this reason, a registration number was not obtained.

3. Ethics:
Research involving human subjects (including human material or human data) that is reported in the manuscript must have been performed with the approval of an appropriate ethics committee. Research carried out on humans must be in compliance with the Helsinki Declaration (http://www.wma.net/en/30publications/10policies/b3/index.html). A statement to this effect must appear in the Methods section of the manuscript, including the name of the body which gave approval, with a reference number where appropriate.
Response: The statement is included in the methods

4. Consent:
Please state in the Methods section whether written informed consent for participation in the study was obtained from participants or, where participants are children, a parent or guardian.
Response: We now indicate in the methods that a waiver for informed consent was approved by our Children’s National Health System Institution Review Board.

5. Conclusions:
Please include a conclusions section on the main manuscript. This should state clearly the main conclusions of the research and give a clear explanation of their importance and relevance. Summary illustrations may be included.
Response: A conclusion section was included

6. Authors’ Contributions:
We suggest the following format (please use initials to refer to each author’s contribution): AB carried out the molecular genetic studies, participated in the sequence alignment and drafted the manuscript. JY carried out the immunoassays. MT participated in the sequence alignment. ES participated in the design of the study and performed the statistical analysis. FG conceived of the study, and participated in its design and coordination and helped to draft the manuscript. All authors read and approved the final manuscript.
Contributors who do not meet the criteria for authorship should be listed in an acknowledgements section. Examples of those who might be acknowledged include a person who provided purely technical help, writing assistance, or a department chair who provided only general support.
Response: We revised the Author’s contributions as suggested

7. Tables:
You have uploaded the tables as additional files. Please remove them from the submission system and include the tables within the text file of the manuscript after the references. The tables should be formatted using the Table tool in your word processor. Please also move the table title to above the table and the legend to below the table, within the text.

Response: The tables were included in the manuscript