Author’s response to reviews

Title: Gut microbiota in children with type 1 diabetes differs from healthy children: a case-control study.

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Author’s response to reviews:

The Editor,
BMC Medicine
20 December 2012
Ref: Gut microbiota in children with type 1 diabetes differs from healthy children: a case-control study (MS: 1845900297788147).

Dear Editor,

We really appreciate the referee’s comments about our revised manuscript. As you suggested, we have addressed the comments in the revised manuscript and we set out below our point-by-point responses to these comments. We also want to indicate that at the end of this cover letter we have included the parental and guardian consent.

Yours sincerely,
Dr. María Isabel Queipo-Ortuño
Responses to the editor comments for MS: 1845900297788147

Comment 1. Please check the author names, institution and email addresses as follows: http://www.biomedcentral.com/bmcmed/authors/instructions/researcharticle#formatting-abstract
Response: We have checked the names, institution and email addresses of all authors and we have verified that all is correct.

Comment 2. Please provide parental and guardian consent as follows: Informed consent must be documented. Manuscripts may be rejected if the editorial office considers that the research has not been carried out within an ethical framework, e.g. if the severity of the experimental procedure is not justified by the value of the knowledge gained.
Response: We have provided at the end of this cover letter a new copy of the parental and guardian consent that was sent in the last revision of this manuscript. Moreover, as was indicated by the editor in her last e-mail of November 28 we have added a short statement in the methods section stating that written guardian/parental consent was obtained.

Comment 3. Please check the author contributions and provide correct initials for Federico F Soriguer.
Response: We have checked the author contribution and the acknowledgements and we have described them following the style suggested by the editor. We have only considered authors the researches who have made substantive intellectual contributions to the manuscript. Moreover, we have corrected the initials of the author Federico F Soriguer (FS) and we have listed the source(s) of funding for the study and for each author in the acknowledgements section.

Comment 4. Please ensure the manuscript adheres to STROBE guidelines for case-control studies as follows: http://www.strobe-statement.org/index.php?id=available-checklists
Response: We have checked that our manuscript fulfills the STROBE guidelines for case-control studies.

Comment 5. Please also ensure that your revised manuscript conforms to the journal style (http://www.biomedcentral.com/info/ifora/medicine_journals ). It is important that your files are correctly formatted.
Response: We have revised our manuscript and it conforms to the journal's style.

PARENTAL AND GUARDIAN CONSENT

PATIENT INFORMATION

Before signing the informed consent, read this information carefully and realize the necessary questions

Nature: We will carry out a comparative study of intestinal microbiota between patients suffering from type 1 diabetes mellitus and healthy controls. For the
analysis of intestinal microbiota stool samples of patients with diabetes and healthy subjects will be required. These samples will be processed and analyzed for later comparison. In addition, a blood sample will be also required to analyze the relationship between the intestinal microbiota and biochemical markers in both the type 1 diabetic children and the healthy children.

Importance: Experimental studies have found significant differences between the intestinal flora of mice suffering from type 1 diabetes mellitus and healthy mice. So, changes in the type 1 diabetes debut and evolution by modifying the intestinal flora with antibiotics treatments have been found. If we prove the existence of significant differences in our work, it could open new research that will help us to understand the pathogenesis of this disease as well as its intervention from a preventive point of view.

Implications for the patient:
- Participation is entirely voluntary.
- The patient may leave the study when they choose, without explanation and without impacting their care.
- All personal data obtained in this study are confidential and they will be treated following the Organic Law of Protection of Personal Data 15/99.
- The information collected will be used only for the specific scientific purposes of this study.
- There are no risks associated with the research for the patients.

If you require additional information you can get in touch with Dr. Leiva Gea in Diabetology Unit of Hospital of Jaén or email isabeleiva @ hotmail.

PARENTAL AND GUARDIAN CONSENT

Title: Gut microbiota in children with type 1 diabetes differs from healthy children: a case-control study
Name of patient:
Name of legally responsible:
I have read the information document that accompanies this consent and I have been able to do questions about the study
I have received enough information about the study
I have talked to the informant clinician: Isabel Leiva Gea
I understand that my participation is voluntary and I am free to participate or not in the study.
I have been informed that all data collected in this study will be confidential and they will be treated in accordance to the Organic Law of Protection of Personal Data 15/99.
I have been informed that the information obtained in this study will be used only
for specific scientific purposes.
I want to be informed of my biochemical data and other personal information obtained in the course of the investigation, including unexpected discoveries, when the information is necessary to prevent serious prejudice for my health or the health of my biological family.

Yes No
I understand that I can leave the study:
- When I want.
- Without explanation.
- No impact on my medical care.

I freely give my consent to participate in the project entitled: Gut microbiota in children with type 1 diabetes differs from healthy children: a case-control study
Signature of patient (or legally responsible if applicable)
Name and surname:
Date:
Signature of the informant clinician:
Name and surname:
Date: