Author’s response to reviews

Title: Efficacy and tolerability of PEG-only laxative on faecal impaction and chronic constipation in children: a randomized controlled study vs a standard PEG-electrolyte laxative.

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To the EDITOR-IN-CHIEF 12 May 2012

BCM Pediatrics

We are hereby re-submitting a manuscript entitled "EFFICACY AND TOLERABILITY OF PEG-ONLY LAXATIVE ON FAECAL IMPACTION AND CHRONIC CONSTIPATION IN CHILDREN. A CONTROLLED RANDOMIZED STUDY VS A STANDARD PEG-ELECTROLYTE LAXATIVE" - F. Savino M.D. Ph D, S. Viola M.D., E Maiullari M.D., G. Di Nardo* M.D., S. Oliva* M.D. and S. Cucchiara* M.D. Ph D

...for publication as Research Article in BCM Pediatrics.

As required, we have added information about the Ethical Committee as follow:
The study was reviewed and approved by the Ethics Committee of “La Sapienza” University of Rome (Italy)

We have inserted information about the study products as follow:
The experimental products (no profit) were supplied free of charge by PROMEFARM srl (Milano, Italy); (Section Methods, page 5).

Further we declare, as competing interest, that the experimental products (no profit) were supplied free of charge by PROMEFARM srl (Milano, Italy);

Constipation is a very common childhood worldwide. The condition is chronic in more than one third of patients and is a common reason for referral to secondary care, in 90-95% of children, constipation is functional, which means that there is no objective evidence of a pathological condition and is related to a diet.

Different PEG-based laxatives with or without electrolytes are available on the market. All PEG-based formulations have been shown in placebo-controlled and active comparator trials to be safe and effective in the treatment of chronic constipation in children. However, there is insufficient information regarding the comparison of other features such as tolerability, palatability and ease of administration between PEG formulations which may influence adherence and, in turn, provide better constipation management in children.

A new PEG 4000-only laxative with no excipients or flavourings in a tasteless, odourless
powder that can be mixed with water or any other common beverage has been recently introduced in the market.

The article describes an original randomized trial randomized study was to compare the efficacy, tolerability, acceptance and compliance of a new PEG-only formulation compared to a reference PEG-electrolyte formulation in resolving faecal impaction and in the treatment of chronic constipation.

These data have not been published previously and are not under consideration for publication by any other journal. All authors have read and approved the version of the article being submitted.

Looking forward to hearing from you,

Yours sincerely,

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