Author's response to reviews

Title: Omega-3 fatty acids for treatment of non-alcoholic fatty liver disease: design and rationale of randomized controlled trial.

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To
The Editors
BioMed Central Pediatrics

Dear Editors,

Please find enclosed our manuscript “Omega-3 fatty acids vs placebo for treatment of non-alcoholic fatty liver disease in children – trial design” by Wojciech Janczyk et al., which we would like to submit for publication as a original article in the BioMed Central Pediatrics.

There is a growing interest in the non-alcoholic fatty liver (NAFLD) which has become the most common cause of chronic liver diseases. Natural history of NAFLD shows progression to steatohepatitis (NASH), liver fibrosis and cirrhosis. Children with NAFLD/NASH are of particular concern, as the early onset of liver disease increases risk of severe complications in later life. Therefore effective and safe treatment for children with NAFLD is urgently needed.

We designed a multi-center, randomized, placebo-controlled, double-blind clinical trial to assess efficacy of omega-3 fatty acids in the treatment of children with NAFLD. So far only few randomized trials tested pharmacological agents in NAFLD in children, only one of them used omega-3 fatty acids. In addition to our knowledge, there are no available study designs describing use of omega-3 in NAFLD for both children or adults in the literature. Creation of the study protocol was preceded by a systematic review of literature of pharmacological treatment in NAFLD (Socha P. et al, JPGN 2008). Hypothesis of potential efficacy of omega-3 fatty acids studies in NAFLD was based on a few promising pilot studies and proven benefits of omega-3 use in metabolic syndrome-related diseases. Trial design of our study was based on the existing randomized clinical trials in diet-related diseases and chronic liver disorders, with respect to specificity of the pediatric age and CONSORT/SPRIT statements.

We believe our manuscript would appeal to the readership of the BMC Pediatrics. With the submission of this manuscript we confirm that this paper has not been published elsewhere and is not under consideration by another journal. All authors had an active part in the final manuscript, approved the manuscript and agreed with its submission to BioMed Central Pediatrics. We confirm that all the research meets the ethical guidelines, including adherence to the legal requirements of the study country.

We look forward to hearing from you at your earliest convenience.

With kind regards
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