Author's response to reviews

Title: Oral disease in adults treated with hemodialysis: Prevalence, predictors, and association with mortality and adverse cardiovascular events: The rationale and design of the ORAL Diseases in hemodialysis (ORAL-D) study, a prospective, multinational, longitudinal, observational, cohort study

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Author's response to reviews: see over
Dear Hayley,

Re: MS: 4865864618509604

We wish to let you know about the changes we have made to the manuscript for the Oral Diseases in hemodialysis (ORAL-D) study we have submitted to BMC Nephrology (MS: 4865864618509604) following detailed editorial requests.

1. Ethical Approval

We have now specifically included information about the ethics approvals required and approved for this study. We have included specifically the following text in the manuscript on page 6:

We received ethics approval for the ORAL Diseases in Hemodialysis (ORAL-D) study from the following responsible local Human Research Ethics Committees: Comité de Protection des Personnes Sud-Mediterranée II (France), Komisja Bioetyczna, Slaskiego Uniwersytetu Medycznego W Katowicach (Poland), CE da Diaverum Portugal (Portugal), Comite Etico de Investigacion Clinica (CEIC) de la Fundaction Puygvert and Agencia Valenciana de Salud, Departament de Salut Valencia (Spain), and Szegedi Tudomanyegyetem, Szent-Gyorgyi albert klinikai kozpont, and Regionalis human orvosbiologiiai kutataseitkai bizottsaga (Hungary). Ethics approval was not required for this type of study in Italy or Argentina. According to the Italian Republic Determination of the Italian Medicines Agency of March 20, 2008 [in Italian], Official Gazette of the Italian Republic, General Series No. 76; March 31, 2008, the ethics committees have only to be informed in writing about the start of the study by the promoter (Consorzio Mario Negri Sud, S. Maria Imbaro, Ch, Italy). All participants provided written and informed consent prior to study initiation and patient enrolment. The study is performed in accordance with the 2000 Edinburgh, Scotland Revision of the Declaration of Helsinki, applicable ICH guidelines and Guidelines on Research Practice.

We will also forward the scanned copies of all ethics approvals to your team by email.

Sincerely,

Giovanni Strippoli

On behalf of the study authors