Author's response to reviews

Title: Family physician and endocrinologist coordination as the basis for diabetes care in clinical practice

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

I send you the revised form of the m.n FAMILY PHYSICIAN AND ENDOCRINOLOGIST COORDINATION……., to BMC Endocrine Disorder. Thank you very much for their appreciate comments.

According to reviewers comments the statistical study and sample size estimation has been recalculated.

Initially, for sample size calculation, the hypothesis that will be no difference between FP and specialist care in relation to primary composite end-point difference of percentage of diabetic patients with progression of peripheral vascular disease and mortality during planned median follow up period of 60-months has been used. Sample size adjusted for drop.outs of 120 subjects powered to detect a 20% difference between groups.

For this planned middle-road 30-months analysis two hypotheses has been tested in order to estimate power of the study. For the hypothesis that there will be no difference between FP and specialist care, a primary end-point HbA1c value has been used.

Previous studies (DCCT, UKPDS, Steno...) reported differences of 0.7% in HbA1c values between groups, 10% of our HbA1c baselina values. With 41 subjects in each group, the study had 90% power for difference=0 versus difference=0.72, taking in mind: type alternative: not equal; -alpha risk 5%; -Sigma 1.0 (known) (Statgraphics Plus for Windowsa 5.1, Statistical Graphics Corporation, Manugist Inc. MD, USA 2000: www.statgraphics.com). In addition we estimated sample size for the hypothesis that there will be no inferior FP treatment in relation to specialist care. A primary end-point difference of percentage of diabetic patients achieving HbA1c <6.5% more than 20% has been used. In this case, with 60 patients in each group, the study had 89% power at 5% significance to detect a clinically significance difference (20%) to be no inferior FP group versus specialist care group.

These comments are inserted in the m.n. p. 6. last paragraph: For sample size calculation for the hypothesis that there will be no difference between FP and specialist care, a primary composite end-point difference of percentage of diabetic patients with progression of peripheral vascular disease and mortality during planned median follow-up period of 60.months has been used. Sample size adjusted for drop-outs of 120 patients powered to detect a 20% difference between both groups. For this planned middle-road 30-months analysis, the sample size was estimate in two ways. For the hypothesis that there will be no difference between FP and specialist care in Steno and ATP III goals, a primary end-point difference in HbA1c value has been used in order to estimate sample size. From previous studies (UKPDS, DCCT, Steno) differences expected in HbA1c levels between control group and experimental group were about 0.7%, being 10% of HbA1c baseline values in our study. With 41 subjects in each group, the study had 90% power at 5% significance (2-sided) for difference=0 versus difference=0.72, to detect a clinically significance difference (10%) in the HbA1c value between both FP group and specialist care group. In addition we estimated sample size for the hypothesis that there will be no inferior FP treatment in relation to specialist care. A primary end-point difference of percentage of diabetic patients achieving HbA1c <6.5% more than 20% has been used. In this case, with 60 patients in each group, the study had 89% power at 5% significance to detect a clinically significance difference (20%) to be no inferior FP group versus specialist care group.

In addition, p values 0.05 and 0.01 are displayed.
The screening foot-care programme has been described elsewhere, references 19 and 20. We insert “consecutively”: p. 6, 2nd paragraph: Between January 2003 and June 2004, 924 diabetic patients consecutively recruited for…..

Informed consent was considered not necessary because all patients received treatment according to guidelines which are annually revised. These guidelines not include the level where patient should be treated, mainly recommended at primary level. This current study used the same treatment and management goals in both levels.

We insert: p.6, 1st paragraph: All patients received treatment according to these guidelines which are annually revised. These guidelines not include the level where patient should be treated, because an informed consent was considered not necessary. The study was conducted according with the Declaration of Helsinki and with the consort…..

The footnote of each figure and table denote Group A, diabetic patients treated by endocrinology service, and Group B, diabetic patients treated by coordinated team, family physicians and endocrinologist, at primary care site. We think that other labels as suggested by rev. 3 could be confounding because primary level and coordinated primary level are not the same.

We think according to reviewers that the m.s. is suitable to be published in BMC Endocrine Dis.

Sincerely
Alfonso L. Calle-Pascual, MDPhD