UNIVERSITY OF BERGEN
Department of Clinical Medicine

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Biostatistics Review Certificate

The sample size required in each arm of the previously published trial was calculated by assuming that a placebo effect was 40% and an effect response was 80%. The total sample size was estimated to be 60 patients, with 20 in each arm (α=0.05, 1-β=0.80)[12]. In the present study a new calculation for the sample size was done based on the response rates obtained from our previous RCT[12]. Thus, assuming that the females' response is 90% and males' response is 60%, The total sample size was estimated to be 22 with 11 females and 11 males (α=0.05, 1-β=0.80). The 30- and 60-g superdonor-faeces groups were pooled together and called the active treated group in order to increase the sample size and reduce the probability of type-II statistical errors. Differences in response and dysbiosis between females and males in the placebo and the active treated group were analysed using the χ^2 test. Differences between females and males in the total scores on the IBS-SSS, FAS and IBS-QoL, and in faecal bacteria and SCFA levels were analysed using the Mann-Whitney test. These analyses were performed using GraphPad Prism (version 8, La Jolla, CA, USA).

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