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Contributions: AR, BB, WW, and OM designed the study. AR, BB, FN, GM, and WW were trial coordinators. IO, and WK did laboratory tests. AA, AR, BB, FN, GM, MS, OM, TK, UK, and WW recruited patients for the BFM-trials. UM, MZ and CS established the dataset. MZ performed statistical analysis. AR, BB, MZ, WW, and OM analysed data. BB, WW, and OM wrote the paper. OM had full access to all the data in the study and had final responsibility for the decision to submit for publication. All authors reviewed the draft of the paper submitted for publication.