Concerning EUDRACT 2020-001614-38

A randomized, open-label, adaptive, proof-of-concept clinical trial of new antiviral drug candidates against SARS-CoV-2 Direct antivirals working against nCoV – Azithromycin treatment stratum (DAWN-AZITHRO)

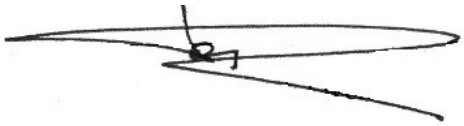
Reason for EARLY TRIAL TERMINATION:

D**ata of RECOVERY's azithromycin-arm became available preprinted online on Medrxiv just prior to the planned 2nd safety review. As these RECOVERY-data did not demonstrate a clear benefit of azithromycin, the trial steering committee and the DSMB questioned if further inclusion of patients in our study was still justified**, especially as some patients would also be eligible for other interventional trials concurrently running in our centre at that time (e.g. DAWn-antico with higher dose anticoagulation + aprotinin + anakinra).

Because we assessed another primary endpoint than RECOVERY (time to clinical improvement instead of mortality), instead of immediately stopping the trial, the DSMB requested to perform **a futility analysis, which was performed when the 15-day follow-up data of the first 160 patients were available**. A total of 187 patients were randomized by that time. Recruitment was halted, so that enrolment in other interventional trials could be prioritized, awaiting formal DSMB advice whether or not to early terminate the trial. **Based on the results of these first 160 patients (no significant benefit for primary outcome with a conditional power of less than 1%), the trial was finally stopped for futility.**

PI signature:

Prof Dr. Robin Vos



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