Author’s response to reviews

Title: Preoperative endoscopic versus percutaneous transhepatic biliary drainage in potentially resectable perihilar cholangiocarcinoma (DRAINAGE trial): design and rationale of a randomized controlled trial

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Dear editor, Dr Morawska,

Please find enclosed our manuscript entitled ‘Preoperative endoscopic versus percutaneous transhepatic biliary drainage in potentially resectable perihilar cholangiocarcinoma (DRAINAGE trial): design and rationale of a randomized controlled trial’.

Preoperative biliary drainage is commonly used to create a safer environment prior to liver surgery in perihilar cholangiocarcinoma (PHC), but biliary drainage may be harmful when severe drainage-related complications deteriorate the patients’ condition or increase the risk of postoperative morbidity. The two most commonly used drainage techniques are endoscopic biliary drainage (EBD) or percutaneous transhepatic biliary drainage (PTBD). Previous studies comparing these techniques are flawed by retrospective design and heterogeneity in procedure-site. Prospective studies are therefore needed to confirm the potential benefit of preoperative PTBD compared to EBD.

This manuscript describes the protocol of our randomized trial in patients with potentially resectable PHC and biliary obstruction undergoing preoperative EBD or PTBD. We believe the subject is of interest to the readership of BMC Gastroenterology. Our protocol has not been published and has not been submitted to or accepted by another journal. The manuscript has been seen and approved by all authors. Furthermore, no publications containing the results of the study have been published or submitted. No conflicts of interest are noted by myself or any of the co-authors.

The study is externally funded by the Dutch Cancer Foundation (KWF, grant number UVA 2013-5925). The study protocol has undergone full peer-review by the scientific board of this foundation in February 2013. Since late 2013, the study is ongoing and 20 patients (of a total of 106) have been included so far. We expect increasing inclusion rate since other Dutch academic centres have recently started including.

Thank you very much for considering this paper for publication in BMC Gastroenterology,

Yours sincerely, on behalf of all authors,

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