Author's response to reviews

Title: Fast Track Multi-Discipline Treatment (FTMDT trial) Versus Conventional Treatment in Colorectal Cancer - The Design of a Prospective Randomized Controlled Study

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

We would like to submit the enclosed manuscript entitled "Fast Track Multi-Discipline Treatment (FTMDT trial) Versus Conventional Treatment in Colorectal Cancer – The Design of a Prospective Randomized Controlled Study", which we wish to be considered for publication in BioMed Central, Cancer.

Most of the current studies on enhanced postoperative recovery and shorten hospitalization day for colorectal cancer focus on the laparoscopic approach or fast-track perioperative treatment, which limits to the short-term rehabilitation and economic benefits. In this randomized and controlled study, we initiate a new model “Fast Track Multi-Discipline Treatment” for the combination of laparoscopic surgery, fast-track perioperative treatment and Xelox chemotherapy, which covering the whole colorectal cancer treatment not only perioperative period but also adjuvant chemotherapy period to achieve the whole process enhanced recovery. No published study of the Fast Track Multi-Discipline Treatment has been found until now. This original FTMDT trial has been registered at clinicaltrial.gov, ID (NCT 01080547) and the recruitment has begun since April 2010. This article is the present study proposal.

This FTMDT study is on the solid basis of the previous research on the colorectal cancer conducted by Prof. Ding, including the immediate related studies as followings:

1. The "Laparoscopic surgery for the curative treatment of rectal cancer" study with the findings that laparoscopy for rectal cancer was safe and effective, resulting in faster recovery and a similar complication rate compared with open surgery (Surg Endosc. 23(4):854-861, 2009). Through this study, we gain much experience and substantial theory background in developing laparoscopic surgery on colorectal cancer.

2. The "Impact of a laparoscopic resection on the quality of life in rectal cancer patients" study showing that the quality of life benefits due to minimally invasive laparoscopic surgery were evident only in the immediate postoperative period and laparoscopic rectal resection therefore provided only better cosmetic benefit over the long term(Surg Today. 40(10):917-922. 2010); and this study stimulated our consideration of integrating the chemotherapy into FTMDT study to earn the long-term benefits.

3. "The interim analysis of an open nonrandomized prospective study comparing laparoscopic surgery with XELOX chemotherapy and open surgery with mFOLFOX6 chemotherapy for resectable colorectal cancer" study, with the interim analysis indicating that laparoscopic colorectomy with XELOX adjuvant chemotherapy provide faster postoperative recovery and sustained better quality of life throughout treatment. Ann Oncol. 21: viii220. 2010 (suppl 8; abstr 693); With this undergoing study, we value the feasibility potential of the new FTMDT model as the whole process cost-saving and efficacy-gaining colorectal cancer treatment.

The manuscript has not been submitted elsewhere for publication, in whole or in part. All the authors listed have approved the manuscript enclosed. If the manuscript
accepted by BMC Cancer, all of the authors agree to transfer the copyright to BMC Cancer.

According to the advice of BMC Cancer, the manuscript has been revised and uploaded. And the point-by-point description of the changes made are as followings:

1. Both of the evidence of ethical and external funding approvals are provided to the editor as been advised. The independent medical ethics committees of the participating hospitals have approved this FTMDT-trial protocol, with the approval number: 2010LSY No.6. All the procedures of this study are under the oversight of the Chinese Ministry of Health. This study is supported by the foundation of Science and Technology Department, Zhejiang, China (Grant No. 2009C13017) with funding amount of 1,200,000 RMB (about 184,560 dollars). Science and Technology Department, Zhejiang is public government department without any commercial funding.

2. The list of the institutional addresses and e-mail addresses for all authors was added in the Title Page.

3. Section of Authors' contributions was added in the Body Text. The format of the Abstract is revised as Background, Methods/Design, Discussion and Trial registration. And the format of the Body Text is revised as Background, Methods/Design, Discussion, Competing interests, Authors' contributions, Author's information, Acknowledgement and Funding, and References.

Thank you for your attention and consideration.

Sincerely yours,

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