

COLOR



Newsletter

1 June 2019

The COLOR III trial has gained momentum with increasing numbers of included patients and participating centers from all over the globe. We sincerely hope the COLOR III is on the agenda for your rectal cancer patients with ongoing inclusions. To provide the highly needed evidence of the TaTME procedure and of surgical quality related outcomes. Uploading speed of the online platform has increased to allow easier uploading by installing a new server. The Data Safety Monitoring Board has recently audited the progress and safety (SAE incidence) of the trial and agreed to continue.

Valuable collaboration with China

In the last months two high volume expert rectal cancer centers in Asia have been recruiting patients for COLOR III: Friendship Hospital Beijing, prof. Hongwei Yao and Sun Yat-sen Cancer Center Taipei, prof. Peter Chin-chieh Chen. Both with steady inclusion rate, good quality surgery and low SAE incidence.

In the last week, COLOR III study director Jurriaan Tuynman and trial coordinator Stefan van Oostendorp have visited 6 more large centers which passed the pretrial with good results to perform an on-site spot check and initiation presentation. We are happy to inform you that all the centers have put in place a research team, good clinical practice, a set-up to prospectively collect data with signed informed consent by each subject. In addition, the clinical practice meets high standards with presence of a multidisciplinary team and a skilled surgical team who perform TaTME in a two-team approach routinely.

Nanchong Central Hospital, prof. Mingyang Ren; Daping Hospital Chongqing, prof. Wei-Dong Tong; Renji Hospital Shanghai, prof. Qing Xu; First Hospital affiliated to Jilin University, prof. Quan Wang; First Affiliated Hospital of Chongqing medical university, prof. Hongyu Zhang; Queen Mary Hospital Hong Kong, prof. Dominic Chi-chung Foo.



Left to right: Jingjing He, Mingyang Ren, Peter Chen, Quan Wang, Stefan van Oostendorp, Zhongtao Zhang, Jurriaan Tuynman, Dominic Foo, Hungyu Zhang, Qing Xu, Hongwei Yao. (Not on photo Wei-Dong Tong)

In the coming months we expect to welcome more colorectal experts from Asia, Prof Masaaki Ito from Japan, prof Sun Chang Park Korea and prof Choon Seng Chong from Singapore, to open for accrual in COLOR III.

The Collaborative opens a great momentum and is an excellent platform to work together on standardization of surgical procedures, structured training for colorectal cancer procedures and to develop robust data collection including the launch of a new clinical trial COLOR4. This team approach in such high quality and high volume centers will absolutely result in many strong projects and manuscripts. We will have regular meetings together as co-PI's.

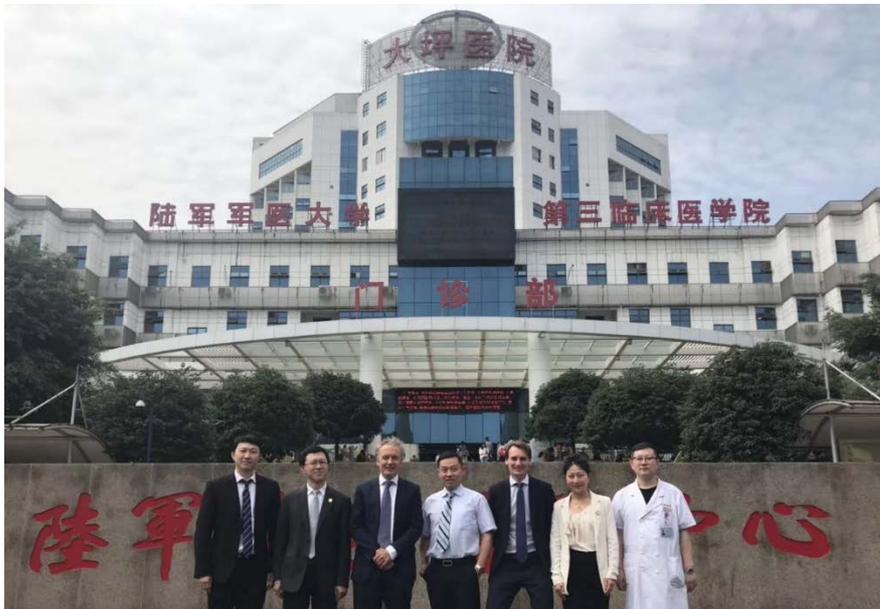
Amsterdam UMC welcomes talented Chinese (young) surgeons for a clinical – research year which will further help development of future projects for the collaborative.

We are looking forward to the expansion of COLOR III in China and coming projects and will visit China in December 2019. On the next pages you will find moments of each center that welcomed us so warm with dedication of so many nurses and doctors

1. The Affiliated Nanchong Central Hospital of North Sichuan Medical College, Nanchong, prof. Mingyang Ren



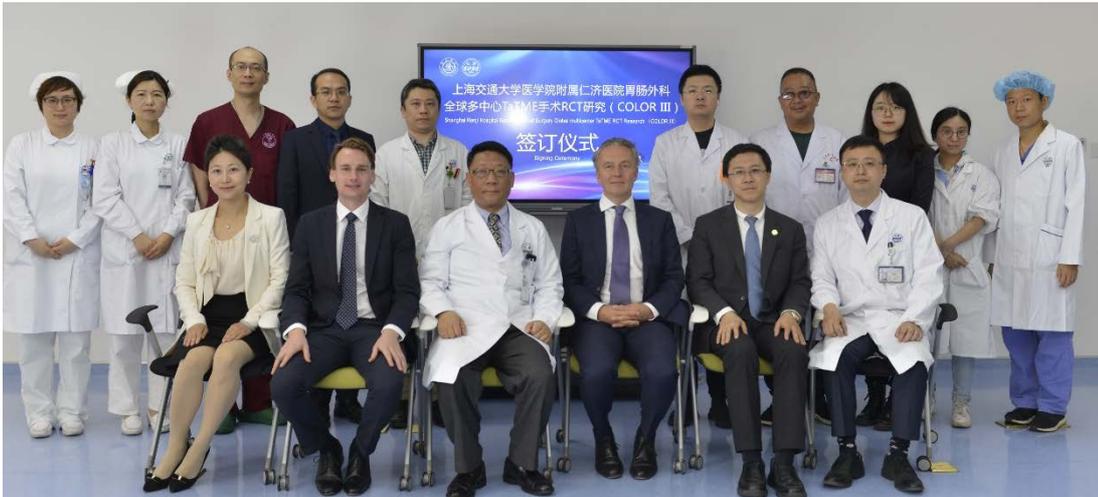
2. Daping Hospital, Army Medical University, Chongqing, prof. Wei-Dong Tong



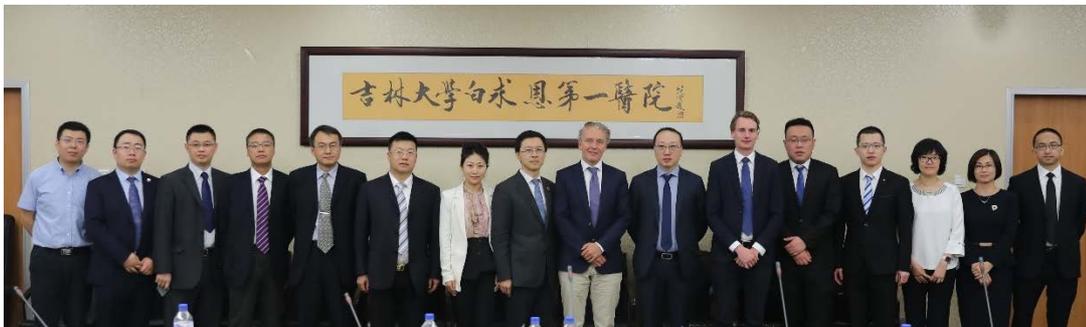
3. The First Affiliated Hospital, Chongqing Medical University, Chongqing, prof. Hongyu Zhang



4. Renji Hospital, Shanghai Jiao Tong University, Shanghai, prof. Qing Xu



5. First Hospital affiliated to Jilin University, Changchun, prof. Quan Wang



6. Queen Mary Hospital, University of Hong Kong, prof. Dominic Chi-chung Foo



General recommendations for the TaTME procedure

After reviewing many TaTME videos we would like to share some findings which need attention:

* Optimal closure of the rectum during surgery. The purse string must be air tight before the rectotomy can be started. However, we have noticed from the video's there is some micro spillage by noticing some mucous. Based upon increasing experience and some recent rumors of recurrence rates we would like to stress this

important point and highly recommend a routine(!) second closure and irrigation after the rectotomy to avoid such micro spillage which might contain viable tumor cells.

* The level of purse strings and resulting anastomosis. We highly recommend if the tumor allows it to place the purse string with a minimal invasive technique above the puborectal sling (the anorectal junction)

* Specimen extraction. This is dependent on the case but a relative high proportion of transanal extraction is observed. In general, we recommend an extraction site through a small Pfannenstiel which is low morbid and potential damage to the marginal artery and seeding is avoided. For those cases that allow transanal extraction a wound protector is necessary.

Generability of the COLOR III RCT results – no selection of only good patients

* Avoid selecting only the best patients for inclusion for COLOR III (a tendency for this approach is noticed in starting centers). We recommend to consecutively ask the patients to participate who meet the inclusion criteria for the COLOR III trial if possible. Only in this way we can demonstrate the real data on TaTME vs lap TME for mid and low rectal cancer.



Conclusion

We want to thank the COLOR III steering committee in China under the leadership of prof. Zhongtao Zhang and deputy chair prof. Hongwei Yao for their efforts to further expand the collaboration. Also we thank Ethicon J&J- China for their support which enabled a highly efficient round-trip. We are looking forward to our joint contribution to COLOR III and future projects in harmonious collaboration!

Stefan van Oostendorp & Jurriaan Tuynman

On behalf of the prof Bonjer and the COLOR III collaborative



Save The Date: Innovations in Colorectal Surgery edition 2020, April 9-11
2-day Scientific program, Hands-on cadaver Course (TaTME, Pelvic Lateral lymph node dissection, ...and more...)
AND a global COLOR III PI-meeting at first day (9 April) before start of scientific program