

COLOR

Newsletter, December 2018

Dear COLOR-III collaborators,

The update of the COLOR-III trial; the multicenter multinational randomized trial to compare transanal TME (TaTME) to laparoscopic abdominal TME. To assess safety it is a non-inferiority design with local recurrence after three years as primary outcome with the small margin of 4% .

Inclusion #100!

The monthly accrual is rapidly increasing and current accrual has reached over 100 patients! In the last months many centers have opened all over the globe; Prof. Peter Chen from Taipei has registered 12 patients in 3 months, dr. Felix Aigner (Charité Berlin) has included 5 cases and the recently opened Ammerland Klinik by dr. Deeb has registered 3 patients already with some more announced! Dr Michal Pędziwiatr (Krakow, Poland) was the lucky one to include the 100th COLOR III patient. Top include is Colin Sietses from Gelderse Vallei hospital: already 29 registered patients for COLOR III!

Necessity of the trial

Latest news of the northern countries includes concern about recurrence rates. This is currently under investigation but this underlines the importance to conduct this trial. In order to demonstrate that the procedure is potentially better but most importantly safe, this trial is powered upon the endpoint 3 year recurrence rate. To demonstrate this a high sample size of 1100 patients is needed to achieve a margin of 4%. That is why we have global collaboration to achieve this!

Expansion of COLOR III

In the first year of opening COLOR III for accrual the COLOR III infrastructure (phase 1) has been tested; Now we are in phase 2 which is global expansion of the RCT. The design of the trial which encompasses an unseen central quality assurance! Including both the MRI at start and the MRI at three years and including the surgical video and pathology.

The central data collection the process from intention to join the trial and actually accrual is a larger hurdle than foreseen. By collecting not only Case record form data and quality of life questionnaires but actual raw patient data such as the MRI images, surgical video and specimen photos the IRB's

and Privacy officers are reluctant with rapid approval. Nevertheless a constant flow of centers is starting the pretrial quality assurance and subsequent entry of the randomization phase of COLOR III.



New sites which opened centers for inclusion in the last year:

- Portugal - Hospital de Braga, Pedro Leao
- Canada - Health Sciences North Sudbury, Antonio Caycedo-Marulanda
- USA - UMASS Worcester, Justin Maykel
- Taiwan - Sun Yat-Sen Cancer Centre Taipei, Peter Chien-Chih Chen
- Austria - Krankenhaus Barmherzige Brüder Graz, Gerald Seitingner
- Germany - Caritas St. Josef Regensburg, Alois Fürst
 - Charité Berlin, Felix Aigner
 - Ammerland Klinik, Muneer Deeb
 - Johanniter Klinik Bonn, Andreas Türler
- Poland - Uniwersytet Jagielloński Collegium Medicum Krakow, Michal Pędziwiatr
- Netherlands - Deventer hospital, Koen Talsma

Formal approval (local IRB and/or Ethical committee) was obtained by prof Antonio Lacy (Barcelona, Spain), prof Andrea Muratore (Agnelli hospital, Italy) and prof van Nieuwenhove (Gent, Belgium). More sites in Hongkong, Australia, Italy, Netherlands, Germany and Spain have requested for approval or are collecting videos for the Pretrial surgical quality assurance.

China - A *special note* for the collaboration with Professor Hongwei Yao and professor Zhongtao Zhang from Friendship Hospital Beijing, China. In April 2018 prof Hongwei Yao, chair of Chinese taskforce of TaTME, showed interest in joining COLOR III. In the past months Professor Bonjer and dr Tuynman have visit China to initiate the COLOR III expansion to China mainland. As of 14 December

2018, requirements for inclusion of patients into COLOR III have been met and Beijing Friendship hospital is open for patient accrual!



COLOR III Steering Committee in China: Prof. Zhongtao Zhang (Chair), Prof. Minhua Zheng (Co-Chair), Prof. Hongwei Yao (Deputy Chair) and Prof. Jingjing He (Int Coord)

Welcome of Professor Twisk as trial statistician

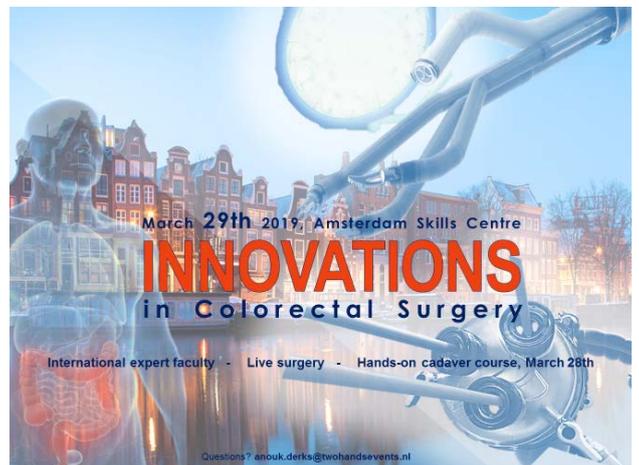
Professor dr. Jos Twisk has agreed to join the COLOR III trial as trial statistician. We are honored to have the head of the statistics department as our consultant statistician.

March 29th 2019 – Innovation in Colorectal Surgery Congress

Our group is excited to host a special colorectal symposium in Amsterdam. With successful previous congresses (2015 and 2017) and continuous TaTME course program, a 1 day training for TaTME, lateral Lymph node dissections and D3 colon surgery will be given on the 28th march and the day after a symposium on high end - innovative topics in the field of colorectal surgery will be held. The new Amsterdam training center will be the avenue.

An international expert faculty is present and special lectures on innovation in colorectal surgery will be given together with live demonstrations. This congress will be followed by a COLOR III investigator meeting on Saturday, March 30th , and we will demonstrate and emphasize the importance of high-level evidence for safe widespread implementation of TaTME for rectal Cancer.

Website: www.innovations.amsterdam



PROGRAM

Live surgery during all sessions

Opening

LESS minimal invasive surgery

Transvaginal and NOTES colorectal surgery – t.b.a.
Advanced TA applications – Prof. dr. Bemelman
TAMIS Pouch IBD surgery – Dr. Warusavitarné

Advanced TME

Innovations in robotic surgery – Prof. dr. Ng
COLOR III trial: TaTME vs Lap TME – Dr. Sietses
Minimal invasive ELAPE – Dr. Chien-Chih Chen
Anatomy guidance in surgery – t.b.a.

Media in colorectal surgery

Twitter and social media in surgery – Dr. Brady
Deferred live – Dr. Knol
Telementoring / AIS-channel – Prof. dr. Lacy

Organ preservation

Neoadjuvant immunotherapy for CRC – Dr. Chalabi
Wait and See – Prof. dr. Beets
LIMERIC trial – Dr. Van Westreenen
Rectal preservation TESAR/STARTREC – Dr. Tuynman

Advanced imaging

Fluorescence guided imaging in CR surgery – Dr. Hompes
MAB fluorescence for tumor detection – t.b.a.
Molecular imaging / advanced imaging – Prof. dr. Kneist
Future of image guided surgery – Dr. Chand

Significance of D3 colorectal resection

The mesentery and D3 registry – Dr. Aigner
D2 with CME sufficient – Prof. dr. Tanis
Significance of lateral lymph nodes – Dr. Kusters
Rectal D3 & LN dissection – Prof. dr. Ito

Training and education

Amsterdam Skills Centre – Prof. dr. Bonjer

What Innovations in Colorectal Surgery

Where Amsterdam Skills Centre

Who International audience

Thursday March 28th Hands-on cadaver course (limited space)

Friday March 29th Congress

Organizing Committee

Jurriaan Tuynman, Colin Sietses, Roel Hompes,

Stefan van Oostendorp, Nina Sluiter



Amsterdam UMC



COLOR

Conclusion

COLOR III collaborative sets a new standard in quality control for surgical randomized clinical trials. The effort of all colorectal surgeons worldwide who want to be part of this collaboration is amazing. Our aim is to provide the surgical community with high level evidence to improve patient care in a safe way. We thank the support of all the participating PI's, residents, research coordinators, study nurses, funding industry and patients for their continuous contribution to COLOR III!

With kind regards,

Professor HJ Bonjer

Jurriaan Tuynman

Stefan van Oostendorp - trial coordinator