NEWSLETTER

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COLOFON

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Voorwoord

Beste CRC onderzoekers,

Terug van het zomerreces sturen we graag weer een nieuwsbrief van de DCCG met de gebruikelijke updates van de verschillende multidisciplinaire studies in Nederland. Daarnaast hebben we al eerder aangekondigd dat we in overleg met het KWF zijn om alleen studies in aanmerking te laten komen voor financiering als ze door de DCCG als zinvol, haalbaar en niet-concurrerend worden beschouwd. De exacte criteria hiervoor gaan we nog in overleg met het KWF binnenkort vastleggen. Om in ieder geval uw nieuwe studie te kunnen pitchen zullen we 2 oktober rond 17.00 uur een teams vergadering beleggen voor alle DCCG leden. De link en het exacte tijdstip hiervoor volgen binnenkort. De wetenschapsmiddag zal plaatsvinden op de gebruikelijke locatie in Utrecht op maandag 27 oktober.

Daarnaast doet het ons een groot plezier om de masterclass en de DCCG dag onder de aandacht te brengen die dit jaar op 11 en 12 december zullen plaatsvinden. Inschrijving hiervoor zal binnenkort mogelijk zijn.

Tot binnenkort tijdens bovengenoemde bijeenkomsten,

Met vriendelijke groeten,

Hans de Wilt

Aankondiging DCCG bijeenkomsten 2025

DCCG pitchen nieuwe voorstellen 2025

Pitchen nieuwe studievoorstellen: donderdag 2 oktober 2025 om 17.00 uur. Opgeven kan via schnater.dccg@gmail.com

DCCG wetenschapsmiddag 2025

Maandag 27 oktober 2025, locatie Vredenburg19 te Utrecht, van 12.30-17.00 uur. Opgeven kan via schnater.dccg@gmail.com.

DCCG Masterclass en DCCG Dag 2025

11 en 12 december a.s. in het Spoorwegmuseum te Utrecht. Meer info volgt spoedig.

Corporate Support

DCCG corporate activities are funded with corporate sponsorship. The corporate sponsors provide general support and have no influence on activities or policy of the DCCG.

DCCG is pleased to acknowledge the corporate support of:

Silver corporate sponsor

Secretariat

Monique Schnater
Zuiderkruis 160
3902 XD Veenendaal, The Netherlands
Tel: 06-22435712
E: info@dccg.nl/ schnater.dccg@gmail.com
W: www.dccg.nl

This newsletter can be downloaded from the DCCG website.

PLCRC-DOLPHIN

DNA-testing Of Liquid biopsies for Patient care close to Home In the Netherlands

Monitoring treatment response in patients with metastatic colorectal cancer using cfDNA fragmentomics testing: the DOLPHIN trial

Background

The PLCRC-DOLPHIN study is a multi-centre, prospective, observational study to investigate the added clinical value of longitudinal circulating tumor DNA (ctDNA) measurements compared to CT imaging for treatment response monitoring in patients with mCRC. The methodology to detect ctDNA is based on the analysis of cell-free DNA fragments, an approach that can be generically applied independent of access to tumor tissue and independent from tumor mutations (van 't Erve et al., 2024)

Study update

Since its launch in March 2023, the PLCRC-DOLPHIN study has enrolled 500 patients. The initial target of 400 patients was reached in December 2024. Inclusion period was extended until September 2025 for patients included before first-line treatment. Enrollment will close at the end of September 2025. Blood sampling for included patients will continue until mid-March 2026. We thank the PIs and study teams of all participating centers for their ongoing efforts, and we hope to include a few more patients in these final weeks.

Inclusion criteria:

- Metastatic colorectal carcinoma
- Inclusion in PLCRC + informed consent for additional blood withdrawals
- Before start first-line systemic therapy
  - Immunotherapy
  - Targeted therapy
  - (Induction) Chemotherapy

Exclusion criteria:

- Other metastatic malignancies in the past 5 years
- Pregnancy

Patient accrual: 494

Primary endpoint: The association between ctDNA changes and clinically determined treatment response in mCRC patients.

Secondary endpoints:

- Association between ctDNA level changes and clinical, biochemical and radiological response at various timepoints during systemic treatment.
- Prognostic value of (DELFI-TF) ctDNA testing pre-treatment and during treatment (PFS/OS).
- Lead time of ctDNA-testing compared to imaging to detect progressive disease

Principal investigators:

Dr. N.F.N. Kok, department of Surgical Oncology, Netherlands Cancer Institute - Antoni van Leeuwenhoek

Dr. R.J.A. Fijneman, department of Pathology, Netherlands Cancer Institute - Antoni van Leeuwenhoek

Dr. .J.M.L. Roodhart, department of Medical Oncology, University Medical Center Utrecht

Dr. G.R. Vink department of Medical Oncology, University Medical Center Utrecht / Netherlands Comprehensive Cancer Organization (IKNL

Dr. M.J. Lahaye, department of Radiology, Netherlands Cancer Institute - Antoni van Leeuwenhoek

Dr. M.N.G.J.A. Braat, department of Radiology, University Medical Center Utrecht

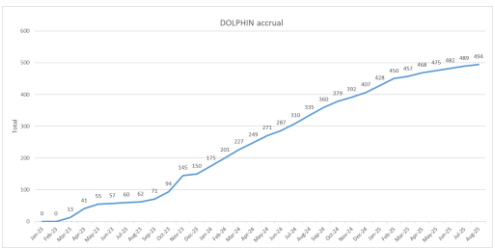
Study coordinator:

Denise van Steijn, Netherlands Cancer Institute - Antoni van Leeuwenhoek

E: d.v.steijn@nki.nl

The following centers are participating in PLCRC-DOLPHIN:

1. Antoni van Leeuwenhoek
2. UMC Utrecht
3. Spaarne Gasthuis
4. OLVG
5. Meander MC
7. Rijnstate
8. RIVAS zorggroep
9. Bernhoven
10. TerGooi MC
11. NWZ
12. St. Jansdal



DOSAGE

A multicenter randomized phase III trial of upfront DOSe-reduced Chemotherapy for Advanced Colorectal Cancer in Older patients

Planned total accrual: 587 patients

Study Objective: To investigate whether upfront dose-reduced chemotherapy is non-inferior to full-dose chemotherapy in older patients (≥70 years) with metastatic colorectal cancer, stratified for expected risk of toxicity.

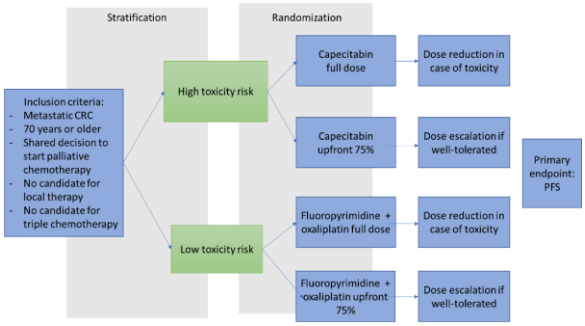
Primary endpoint: PFS

Secondary endpoints: Grade ≥3 toxicity, number of treatment cycles, dose reductions during treatment, cumulative received dose, hospital admissions, QoL and physical functioning, OS and cost-effectiveness

Most important inclusion criteria: Patients aged 70 years or older with metastatic colorectal cancer, who are candidates for systemic treatment according to their treating medical oncologist.

Most important exclusion criteria: Prior palliative chemotherapy or prior adjuvant chemotherapy in the year before inclusion, DPD deficiency, candidates for triple therapy or local therapy.

Study design: Prior to treatment initiation, patients are classified as either "*low*" or "*high risk* of toxicity" based on the oncologist's judgement, advised by the outcome of the Geriatric-8 (G8) screening tool. Patients classified as "*low risk*" are randomized in a 1:1 ratio to receive combination therapy, either at full standard dose or with a 25% upfront dose reduction. Patients classified as "*high risk*" are randomized in a 1:1 ratio to receive monotherapy with capecitabine, either at full standard dose or with a 25% upfront dose reduction.



Participating centers:
A total of 43 Dutch hospitals have already agreed to participate. For participation, please contact DOSAGE@lumc.nl

Principal investigator:
Prof.dr. Johanneke Portielje, Department of Medical Oncology, LUMC
E: DOSAGE@lumc.nl

Monitoring and data management:
Clinical Research Center, LUMC

Study coordinator:
drs. Trishika Binda, Department of Medical Oncology, LUMC
E: t.r.r.binda@lumc.nl
E: DOSAGE@lumc.nl

Study update:

A protocol amendment has been implemented to enhance the study design. In this amendment, the role of the G8 questionnaire has been changed from a decision-making tool to an advisory tool. The treating oncologist now has the final decision regarding treatment with monotherapy or combination therapy. Additionally, 9 new hospitals have joined the DOSAGE trial with this amendment.

At the moment 44 participants have been included in the DOSAGE trial. Of the 43 participating centers, 41 hospitals are open for inclusion. In the upcoming months, the last hospitals will open for inclusion. We would like to thank all participating centers!

OPAXX

OPAXX study: organ preservation in patients with a good clinical response after (chemo)radiation for rectal cancer.

Summary: patients with rectal cancer and a clinically good, but not complete response at the first response evaluation (<14 weeks after the last date of radiotherapy) are eligible for this phase II feasibility study. Patients will be randomised to one of the two additional local treatment options aiming at organ preservation:
contact x-ray brachytherapy (Papillon)
extension of the waiting interval +- local excision (TAMIS).

Primary endpoint: rate of successful organ preservation at one year.

Secondary endpoints: functional and oncological outcomes, morbidity and toxicity of additional local treatment.

Inclusion criteria

- rectal cancer patients treated with neoadjuvant (chemo)radiotherapy;
- clinically near-complete response or a small residual tumour mass <3cm at first response evaluation;
- technically feasible to perform both treatment options (contact x-ray brachytherapy or local excision).

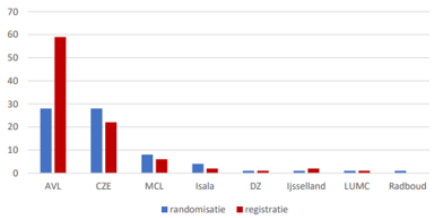
Exclusion criteria

- neoadjuvant or induction chemotherapy prior or adjacent to (chemo)radiation (e.g. Rapido or M1-scheme);
- presence of suspicious lymph nodes (ycN+) at first response evaluation;
- residual tumour >3cm and/or >50% of the circumference of the rectal lumen.

Principal investigators:
Brechtje Grotenhuis, MD, PhD, dept. Surgery, Antoni van Leeuwenhoek
E: b.a.grotenhuis@nki.nl
Pim Burger, MD, PhD, dept. Surgery, Catharina Hospital Eindhoven
E: pimburger@catharinaziekenhuis.nl

Study coordinator:
Charlotte Ceuppens, MD, dept. Surgery,
Antoni van Leeuwenhoek
E: c.ceuppens@nki.nl / waitandseerectum@nki.nl
P: 020-5129111 (sein 1480)

Current status:
Inclusions OPAXX randomisation: 72/168
Inclusions OPAXX registration: 93



In case of a patient with a near complete response, but doesn't meet the inclusion criteria for the OPAXX study: please contact us! We would be happy to include the patient in the OPAXX registration study (M16WAS)

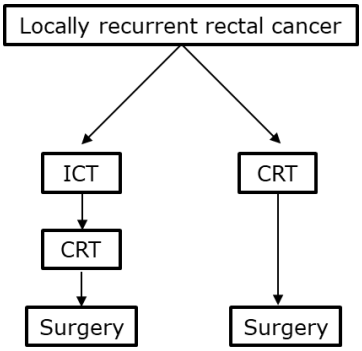
Visit our website for more information:
www.OPAXX.nl

PelvEx II

Per 22 augustus staat de inclusieteller op 256 deelnemers voor de PelvEx II. Sinds het begin van dit jaar maken we gebruik van een countdown-app, waarmee we onlangs de mijlpaal van 250 deelnemers hebben bereikt! We kijken nu vooruit naar de volgende stap: de countdown naar de laatste 100 inclusies. Graag zien we de komende periode weer veel inclusies tegemoet!

Mocht u een patiënt hebben met een recidief rectumcarcinoom, maar twijfelt u of uw patiënt kan deelnemen aan de PelvEx II? Aarzel niet en stel deze vraag bij uw regionale expert centrum. Mocht u andere vragen hebben dan laat het ons weten via het bekende e-mailadres of neem contact met ons op via het vermelde telefoonnummer. Voor verdere vragen en/of opmerkingen omtrent de studie kunt u ons ook op dezelfde wijze bereiken!

Primair eindpunt: R0 resectie ratio



Totaal benodigde inclusies: 364

Inclusies momenteel: 256 per 22 augustus 2025)

Top 3 includerende centra in 2025

1. Catharina Ziekenhuis Eindhoven
2. NKI-AvL
3. Erasmus Medisch Centrum

Project leider

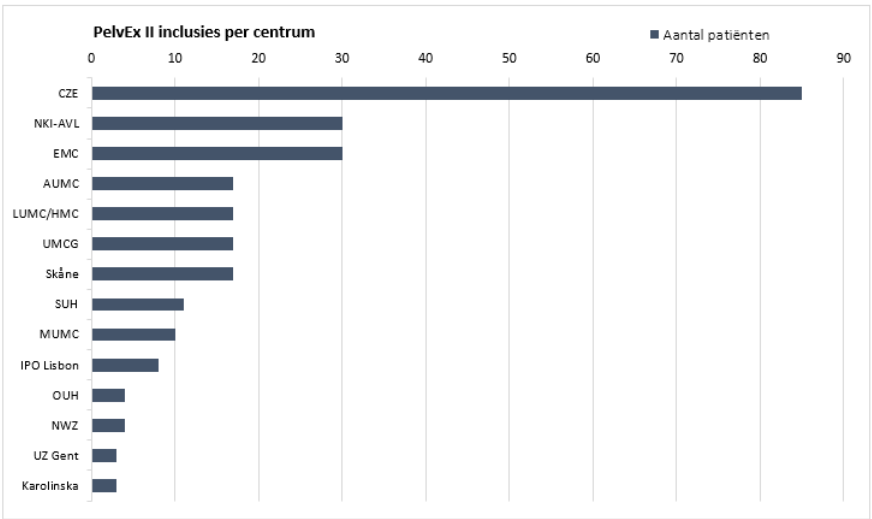
Prof.dr. J.W.A. Burger, Chirurgische Oncologie, Catharina Ziekenhuis Eindhoven

pim.burger@catharinaziekenhuis.nl

Trial coördinatoren

Drs. Fleur Vande Kerckhove, Chirurgie, Catharina Ziekenhuis Eindhoven

pelvex2@catharinaziekenhuis.nl; T: 040-2398858



PLCRC

PLCRC, the Prospective Dutch Colorectal Cancer cohort, is a population-based observational cohort study for all Dutch patients diagnosed with small bowel, colorectal and anal cancer. Aim is to establish a continuous source for a large variety of research purposes. Currently more than 25 studies make use of the infrastructure.

For this project, prospectively collected clinical data are requested from the Netherlands Cancer Registry. Participating patients will also be invited to complete questionnaires on self-reported Health Related Quality of Life (HRQoL) and work ability, and to donate blood and tumor tissue samples for future research purposes. This cohort of lower Gi cancer patients provides an infrastructure for research and can be used for studies, like studies to evaluate the impact of diet and lifestyle on treatment response, or to evaluate new treatment modalities according to the Trials within Cohort design (TwiCs).

Program manager
Dr. A.J.S. van Tetering-Houben
06-29001750
a.j.s.houben@umcutrecht.nl

PLCRC Study team
06-46919566
info@plcrc.nl
www.plcrc.nl

Study update

Number of patients: Per August 2025, the number of 24,591 included patients and 68 participating centers was reached.

Several multicenter sub-studies are ongoing, including (www.plcrc.nl):

-CONCERN: value of ctDNA in patients with early- to intermediate-stage rectal cancer as a real-time marker of response during neoadjuvant chemoradiation and as predictor of regrowth/recurrence during follow-up

- DISTANCE: towards patient-led follow-up after curative treatment of stage II and III colorectal cancer

- DOLPHIN: DNA-testing Of Liquid biopsies for Patient care close to Home In the Netherlands

- **MEDOCC:** prospective observational cohort study to evaluate the prognostic relevance of ctDNA in stage II CRC

- **MEDOCC-CrEATE:** circulating tumor DNA based adjuvant chemotherapy in stage II colon cancer patients

- **OLIPEC**: cytoreduction, HIPEC and local treatment for patients with colorectal peritoneal and limited liver/lung metastases; a parallel cluster trial

- **ORCA:** observational study to explore changes in *RAS* mutation status in ctDNA in patients with *RAS*wt non-liver limited mCRC over time (inclusion completed)

- **SACRA**: lifeStyle And ColoRectal cArcinoma: Integrating lifestyle medicine in the treatment and follow-up of cured colorectal cancer (CRC) patients

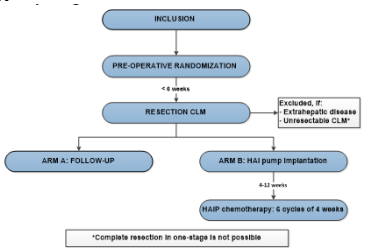
- **VANTAGE**: optimizing minimal invasive surgical techniques for rectal cancer in ‘dedicated centers’: a prospective observational multicenter study.

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PUMP-I trial

A multicenter RCT comparing resection vs resection plus adjuvant hepatic intra-arterial chemotherapy in the liver for patients with resectable colorectal liver metastases and a low clinical risk score.

Study design



Inclusion criteria:

- Resectable index CRLM
- Clinical Risk Score (CRS) of 0-2*
- No (history of) extrahepatic metastases
- No previous local treatment in the liver
- No second malignancy < 5 years ago
- No liver-first resections (synchronous primary and liver resections are allowed)

**Important! Only pN+ status scores a CRS point (not cN+). Nodal status is always considered negative (N0) in case of synchronous primary and liver resection.*

Study coordinators

L. (Loubna) Outmani, MD

Dept. of surgery, Erasmus MC

Mail: l.outmani@erasmusmc.nl

pump@erasmusmc.nl

Tel: +31 624 809 581/+31 107 042 125

Principal investigator

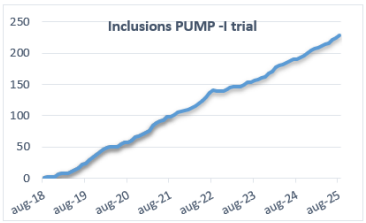
B. (Bas) Groot Koerkamp, MD, PhD, dept. of surgery, Erasmus MC

Mail: b.grootkoerkamp@erasmusmc.nl

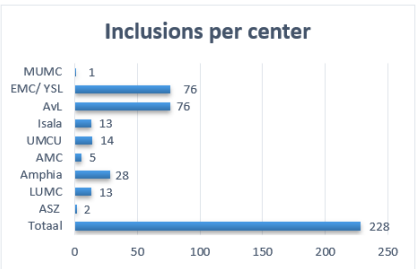
Tel: +31 107 040 234

Study update (August 2025)

Inclusions: 228/230



Inclusions per center:



As of today, we have included 228 of the 230 patients we aim to include. We want to thank everyone for their efforts to complete this study. We need your help to complete this study. We still need 2 patients to fill our trial. If you have a candidate, please do not hesitate to contact or refer the patient to the study coordinators or one of the participating centers.

We have noticed our patients find the information video on the homepage of our website helpful in understanding the trial. Please refer them to the website for additional information.

Website URL: www.chemopomp.nl

Website QR code:

PUMP-IT RCT

Study update

*Hepatic arterial infusion **PUMP** chemotherapy combined with systemic therapy versus systemic therapy alone as **I**nduction **T**herapy for initially unresectable colorectal liver metastases.*

Objective: to investigate whether hepatic intra-arterial chemotherapy combined with systemic therapy (HAIP-SYST) prolongs survival in chemo-naive patients with initially unresectable synchronous colorectal liver metastases.

Primary endpoint: overall survival

Main inclusion criteria:

- Unresectable synchronous CRLM (according to predefined criteria and National Liver Panel)
- No previous systemic therapy for CRC
- Primary tumor in situ and resectable without neoadjuvant treatment
- Suitable hepatic arterial anatomy (GDA connected to one of the liver arteries)

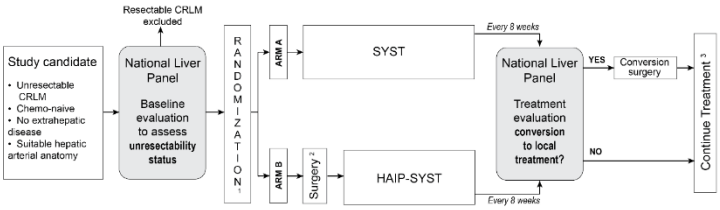
Main exclusion criteria

- Extrahepatic disease
- Previous hepatic resection/ablation/RT
- DPD / MMR deficiency

Potential PUMP-IT candidate?

Please contact the study coordinator for logistics and referral.

Study design



CRLM colorectal liver metastases **SYST** systemic therapy **HAIP-SYST** hepatic arterial infusion pump chemotherapy with systemic therapy

1 Stratification: side primary tumor, *RAS* and *BRAF*^{V600E} mutation status, unresectability status, inclusion center, preference to initiate triplet or doublet systemic therapy if randomised to arm A.

2 Pump placement and resection primary tumor. Preoperative: CT-angiography of the liver. Postoperative: ^{99m}Tc-MAA scintigraphy

3 In case of conversion, the total treatment duration for both arms is 6 months

Accrual status | 24/306

Initiation status | 14/20 participating centers

We would like to thank all participating centers!

Open for inclusion

Antoni van Leeuwenhoek
Albert Schweitzer Ziekenhuis
Amphia
Deventer Ziekenhuis
Erasmus MC
Frisius MC
Jeroen Bosch Ziekenhuis
LUMC
Máxima Medisch Centrum
Medisch Spectrum Twente
Meander Medisch Centrum
OLVG
UMCG
UMCU

Opening soon

Amsterdam UMC IJsselland Ziekenhuis, Isala, Maastricht UMC+, Radboud UMC, Spaarne Gasthuis

Principle investigator
Dr. K.F.D. (Koert) Kuhlmann
k.kuhlmann@nki.nl

Study coordinator
Drs. E.M. (Elisa) ter Kuile
pump@nki.nl / 020 512 9111 (sein 8104)

STARTREC-3

*Can we **S**ave the rectum by watchful waiting or transanal microsurgery following shor**T**-course radiotherapy and **A**dditional local o**R** systemic **T**reatment for early-stage **RE**ctal **C**ancer?*

Study design: The STARTREC-3 is a non-randomized, multicenter, phase 2 platform study aiming to increase organ preservation rates for early-rectal cancer patients by investigating neoadjuvant treatment intensification with SCRT followed by local radiotherapy (either internal radiotherapy boosy by contact X-ray brachytherapy or an external beam radiotherapy boost on an MR-guided linear accelerator) or systemic chemotherapy (in terms of 3 cycles CAPOX), with response evaluations guiding organ preservation feasibility.

Objective: to improve the organ preservation rate for early-stage rectal cancer.

Study population: Patients with early-stage (cT1-3abN0M0) or early-intermediate (cT1-3abN1(≤3 nodes ≤8mm)M0) rectal cancer, of whom the tumor is ≤40mm in size and located in the mid or distal part of the rectum, and with a wish for organ preservation.

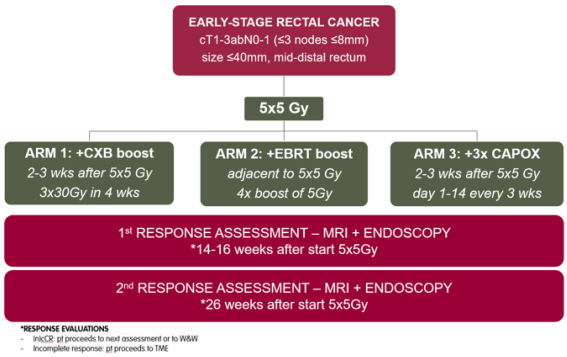
Primary endpoint: the proportion of patients with successful organ preservation at 24 months from the start date of SCRT

Intervention:

1. ARM 1 CXB boost: additional 3 fractions of 30 Gy by means of contact X-ray brachytherapy (CXB).

2. ARM 2 EBRT boost: adjacent to SCRT, additional 4 fractions of 5 Gy will be given on the primary tumour as external boost (by MR Linac or MRIdian)

3. ARM 3 CTx: 3 courses of CAPOX



Study update

One year after receiving METC approval (Aug 2024), patient enrollment is well underway across all study arms. So far, **58 patients** have been included! We would like to thank all participating centers for their efforts.

We plan to open the final 5 study centers in the coming weeks.

STUDY – CENTER	STATUS	INCLUSIONS 58/210
ARM 1 – AvL	*Open*	**17**
ARM 1 – Catharina	*Open*	**14**
ARM 2 – Radboudumc	*Open*	**5**
ARM 2 – Diakonessenhuis / UMCU	*Open*	**1**
ARM 2 – Deventer / RT Deventer	*Open*	**3**
ARM 2 – Rijnstate / RT Deventer	*Open*	**4**
ARM 2 – UMC Utrecht	*Open*	**3**
ARM 2 – MC Leeuwarden / RIF	*Initiation TBD*	-
ARM 3 – LUMC	*Open*	-
ARM 3 – Isala	*Open*	**4**
ARM 3 – Amphia / BVI	*Open*	**5**
ARM 3 – IJselland / EMC	*Open*	**1**
ARM 3 – OLVG / AUMC	*Open*	**1**
ARM 3 – Amsterdam UMC	*Initiation TBD*	-
ARM 3 – ETZ / BVI	*Initiation planned*	-
ARM 3 – Martini / UMCG	*Initiation TBD*	-
ARM 3 – Spaarne Gasthuis	*Initiation TBD*	-

Principal Investigators:

Dr. B.A. Grotenhuis, Surgery, Antoni van Leeuwenhoek

Prof. dr. J.H.W. de Wilt, Surgery, Radboudumc

Prof. dr. C.A.M. Marijnen, Radiotherapy, Antoni van Leeuwenhoek

Study coordinator:

Drs. S.E.N de Vries, Surgery,

Antoni van Leeuwenhoek & Radboudumc

E: s.d.vries@nki.nl / star-trec@radboudumc.nl

T: 020-5129001

TENTACLE – Colon study

TreatmENT of AnastomotiC LeakagE after colon cancer resection

Rationale:

Anastomotic leakage (AL) is a common and severe complication after colon cancer resection, but large comparative studies comparing various treatment strategies are lacking.

Objective:

To evaluate various treatment strategies for AL, and to develop prediction models for 90-day mortality and major morbidity, considering patient, tumor, resection and leakage characteristics.

Study design: An international multicenter retrospective cohort study. All hospitals performing colon cancer resection can collaborate. Collaboration involves identifying patients with AL at our center and entering data into a secure online database. All (up to 4) collaborators will be granted corporate authorship under the name 'The TENTACLE – Colon Collaborative Group' in all manuscripts.

Study population:

Adult patients who developed AL after surgical resection with formation of a primary anastomosis for colon cancer (cT1-4b, N0-2, M0-1).

Primary endpoints:

90-day mortality, and as composite primary outcome 90-day Clavien-Dindo grade 4-5 complications.

Secondary endpoints:

Hospital length of stay, intensive care unit length of stay, number of radiological and surgical reinterventions within one year after resection, mortality (in-hospital, 30-day, and 1 year), comprehensive complications index (CCI), and 1-year stoma-free survival

Study update

The inclusion period has been stopped. A total of 270 centers from 55 countries across 6 continents have been collaborating, which resulted in the inclusion of 3771 patients with an anastomotic leakage.

Principal investigators:

Prof. dr. J.H.W. (Johannes) de Wilt

Prof. dr. P.J. (Pieter) Tanis

Coordinating investigator

Drs. J.M.G. (Jobbe) Lemmens

Radboud University Medical Center

E: info@tentaclestudy.com

TESAR

TESAR: Rectal preserving treatment for early rectal cancer. A multi-centred, partially randomised, patient-preference trial of radical surgery versus adjuvant chemoradiotherapy after local excision for early rectal cancer.

Website: www.tesartrial.nl

Summary In this multicentre, partially randomised, patient preference trial, patients with a complete local excision of intermediate risk T1–T2 rectal cancer can choose between completion total mesorectal excision (TME), adjuvant chemoradiotherapy, or active surveillance.

Primary endpoint Three-year locoregional recurrence

Secondary endpoint Distant metastases, morbidity, disease-free survival, overall survival, stoma rate, quality of life (QoL), and cost effectiveness

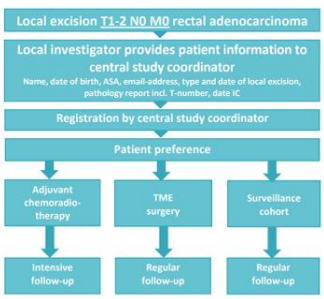
Inclusion criteria

- Indication for completion TME after local excision (TEM/TAMIS/polypectomy/EMR/EFTR/ESD/EID), high-risk T1 or low-risk T2
- R0 resections (margin >0.1mm), Rx resections without macroscopic residual tumour, or R0 re resections following R1 resection with carcinoma in the resection plane
- Adequate distant staging (<6 weeks prior to inclusion) without signs of lyphatic or distant metatases.

Exclusion criteria

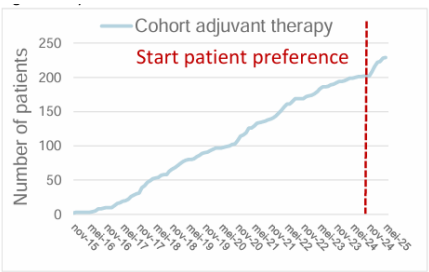
- No current tumor or synchronous colorectal cancer
- No other malignancy (disease free for 5 years)
- No previous pelvic radiation

Flowchart



Study progress

Since the introduction of the patient preference design, patient enrollment in the TESAR trial has accelerated significantly.



Randomised cohort: 202 patients have been randomised to either completion surgery (n = 100) or adjuvant chemoradiotherapy (n = 102).

Patient preference cohort: 41 patients choose completion surgery (n=1) or adjuvant chemoradiotherapy (n=40).

Surveillance cohort: 149 patients, meeting the inclusion and exclusion criteria, have been included in the surveillance cohort.

Participating centers: Amsterdam UMC, Amphia Ziekenhuis, NKI, Bravis Ziekenhuis, Catharina Ziekenhuis, Centre Hospitalier Universitaire, Deventer Ziekenhuis, Diakonessenhuis, Dijklander Ziekenhuis, ETZ, Erasmus MC, Flevoziekenhuis, Gelre ziekenhuis, IJsselland Ziekenhuis, Ikazia, Isala, JBZ, Laurentius, LUMC, Maastro, Medisch Centrum Leeuwarden, MUMC, NWZ, OLVG, Radboud UMC, Radiotherapeutisch Instituut Friesland, Radiotherapiegroep Arnhem, Rijnstate, Spaarne Gasthuis, St. Antonius Ziekenhuis, UMCG, UMCU, Verbeeten Instituut, Ziekenhuis Gelderse Vallei, Ziekenhuisgroep Twente, Zuidwest Radiotherapeutisch Instituut

Contact details

Principle investigator Prof. dr. J.B. (Jurriaan) Tuynman E: j.tuynman@amsterdamumc.nl

Study coordinator Drs. L.R. (Laura) Moolenaar Amsterdam UMC, location VUmc E: l.r.moolenaar@amsterdamumc.nl T: 06-30886252