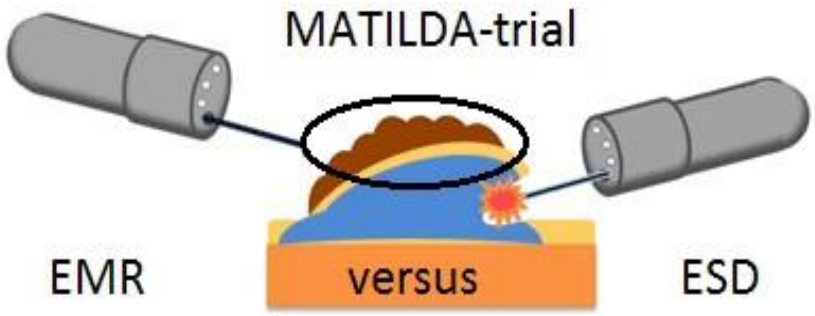
Multicenter, randomised clinical trial comparing endoscopic **M**ucosal resection (EMR) **A**nd endoscopic submucosal dissec**TI**on (ESD) for resection of **L**arge **D**istal non-pedunculated colorectal **A**denomas



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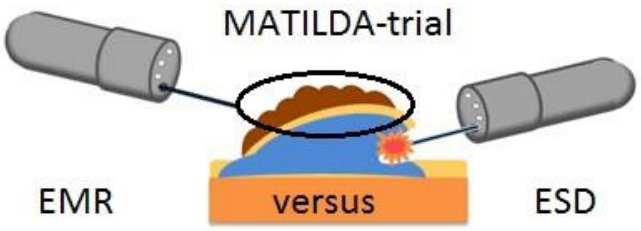


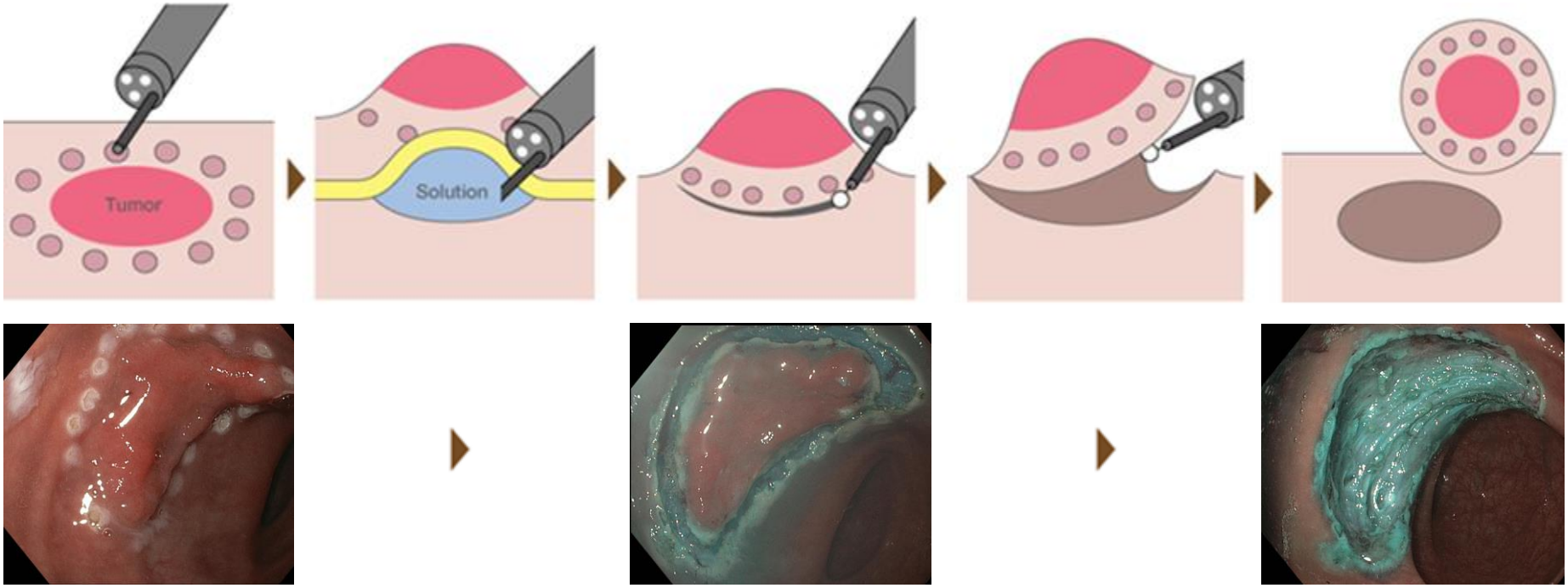
KWF KANKER BESTRIJDING

Sint Franciscus Gasthuis

integraal kankercentrum Nederland

Endoscopic Submucosal Dissection

- Classic ESD
- Hybrid ESD (hESD)



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ESD has some important advantages

EMR

- Relatively easy
- ↓ Procedure time
- ↓ Complication rate
- ↓ R0-resection
- ↑ Recurrence rate

ESD

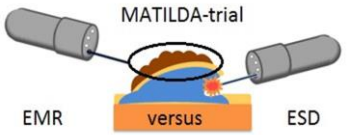
- Learning curve
- ↑ Procedure time
- ↑ Complication rate
- ↑ R0-resection
- ↓ Recurrence rate

Widely available

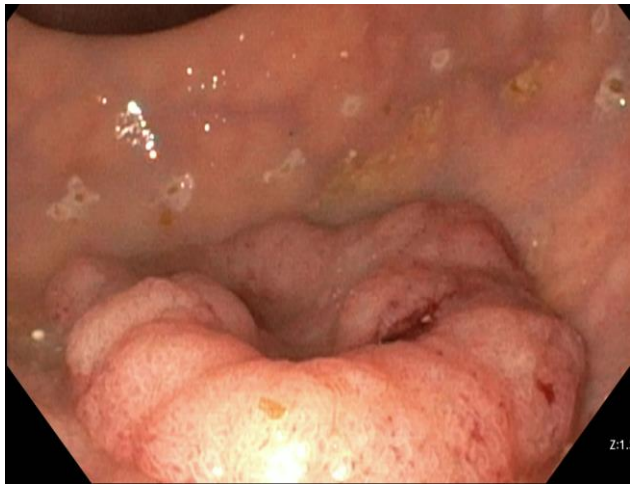
Not yet widely available in Europe

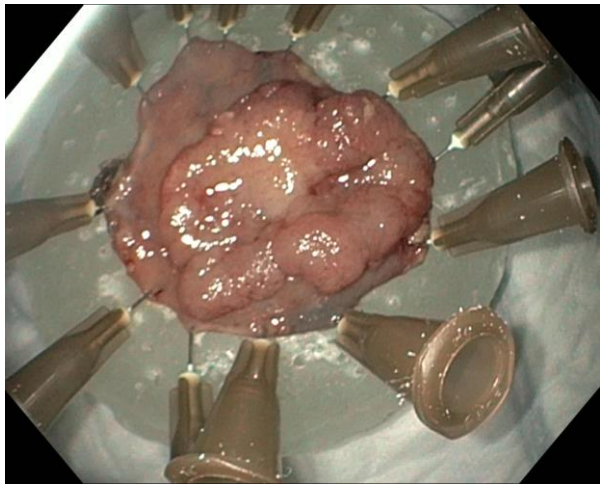
1. Puli et al. World J Gastroenterology 2009
2. Uraoka et al. Dig Endoscopy 2012
3. Moss et al. Gastroenterology 2011

Aim



We aim to evaluate the (cost-)effectiveness of ESD against EMR for resection of large colorectal adenomas on both short (i.e. 6 months) and long-term (i.e. 36 months)





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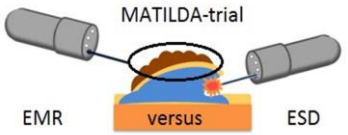
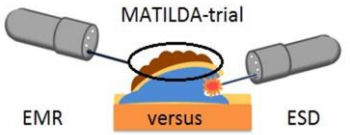
Hypothesis



We hypothesize that in the short-run ESD is more time consuming resulting in higher healthcare costs, but is (cost-) effective and results in a lower patients burden on the long-term due to a higher number of R0-resections and lower recurrence rates with less need for repeated procedures.



Index colonoscopy:

Non-pedunculated distal polyp ≥ 2 cm

Check in- and exclusion criteria

Not eligible → Registration in screeninglog

Fulfills

Informed consent procedure

No consent → Registration in screeninglog

Consent signed

Randomization

EMR | ESD

Follow-up colonoscopy at 6* and 36 months

Endpoints:
- recurrence rate at 6 months (primary endpoint)
- R0-resection rate
- perceived burden & QoL at 36 months
- surgical referral rate at 36 months
- healthcare resources utilization and costs
- complication rate within 30 days
- recurrence rate at 36 months

* Only if recurrence is found at the 6-months colonoscopy, the next follow-up colonoscopy will be planned 6 months later (T=12 months). This is repeated until no recurrence is found with a maximum of three endoscopic resection attempts before referral to the surgeon.

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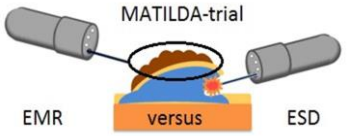
Patients



Inclusion criteria:

- non-pedunculated polyp larger than 20 mm in the rectum, sigmoid or descending colon found during colonoscopy
- indication for endoscopic treatment
- ≥18 years old

Exclusion criteria:

- suspicion of malignancy as determined by endoscopic findings or proven malignancy at biopsy
- prior endoscopic resection attempt
- presence of synchronous distal advanced carcinoma that requires surgical resection
- the risk exceeds the benefit of endoscopic treatment, such as in patients with an extremely poor general condition or a very short life expectancy
- the inability to provide informed consent

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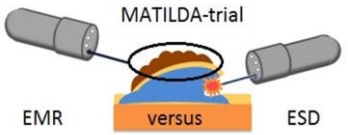
Endpoints



Primary endpoint:

- Recurrence rate at follow-up colonoscopy after 6 months, observed from resected residual disease or, if not present, from biopsies of the scar

Secondary endpoints:

- Complete (R0-)resection rate, defined as dysplasia free vertical and lateral resection margins at histology
- Perceived burden and quality of life
- Complication rate
- Surgical referral rate defined as the number of patients that are referred for surgical management at 36 months
- Long-term recurrence rate at follow-up colonoscopy after 36 months, observed from resected residual disease or, if not present, from biopsies of the scar
- Health care resources and costs

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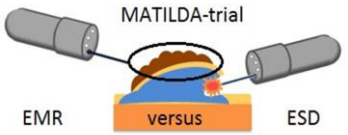
Sample size



- calculated for the primary outcome parameters recurrence rate at 6 months

- recurrence rate: superiority model
  - 2% in the ESD group versus 12% in the EMR group
  - power of 80% and an α of 0.05
  - patients needed: 198

- Correct for patients lost-to-follow-up (7%) → **212 patients** will be included; 106 patients in each arm.

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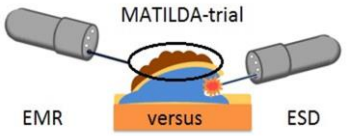
Datamanagement

- Research nurse from IKNL at each site
- Data-extraction from medical record & endoscopy form
- IKNL will send patients (digital) questionnaires on 6 timepoints:
  - baseline
  - 4 days after EMR/ESD
  - 4 weeks after EMR/ESD
  - after the 6 months follow-up colonoscopy
  - 13 months after EMR/ESD
  - after the 36 months follow-up colonoscopy

Don’t forget… study procedures



- Experience level participating endoscopists
  - ESD: >25 colorectal ESDs
  - EMR: >500 EMRs with >50 in polyps ≥2 cm
- After pEMR: adjunct therapy with coagulation
- Opposite colonic wall will be marked with ink
- Resected specimen will be pinned on a paraffin, rubber or cork sheet
- No recurrence? Take biopsies!

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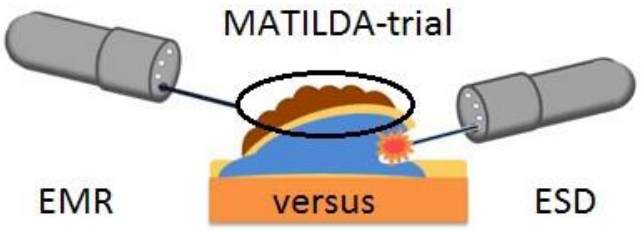

gelre ziekenhuizen

Albert Schweitzer ziekenhuis

meander MEDISCH CENTRUM

Isala klinieken

Diakonessenhuis

deventer ziekenhuis

Groene Hart Ziekenhuis
Open voor iedereen

Ziekenhuis Gelderse Vallei

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KNL integraal kankercentrum Nederland

Ikazia ziekenhuis

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Erasmus MC

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Sint Franciscus Gasthuis

MAASSTAD ZIEKENHUIS

máxima medisch centrum

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