

OPTical diagnosis of T1 Colorectal carcinoma And depth of invasion in Large (≥20 mm) non- pedunculated colorectal lesions

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON20792

Source

Nationaal Trial Register

Brief title

OPTICAL

Health condition

t1 colorectal cancer
optical diagnosis

Sponsors and support

Primary sponsor: University Medical Center Utrecht (UMCU)

Source(s) of monetary or material Support: University Medical Center Utrecht (UMCU)

Intervention

Outcome measures

Primary outcome

Accuracy in predicting T1 CRC and depth of invasion.

Secondary outcome

Accuracy of the individual optical features.

Study description

Study objective

We aim to test the accuracy of Western gastroenterologists in differentiating T1 CRCs from its precursor lesions and subsequently in estimating invasion depth

Study design

Optical diagnosis [1 day]

Intervention

This is a multi-center, prospective, single-blinded trial. All image evaluators participating in this study will be blinded for the final histopathological diagnosis when evaluating the endoscopic features.

Contacts

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Eligibility criteria

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:

- ≥ 18 years old
- Scheduled to undergo colonoscopy
- large (>20 mm) non-pedunculated colorectal lesions suspected to be an adenoma (LGD / HGD) or T1 CRC found during colonoscopy

Exclusion criteria

No exclusion criteria

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Single blinded (masking used)
Control:	N/A , unknown

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	01-09-2015

Enrollment: 343
Type: Anticipated

Ethics review

Positive opinion
Date: 14-01-2016
Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL5427
NTR-old	NTR5561
Other	: 15-435

Study results