LIMited wEdge ResectIon for Colonic T1 cancer - a prospective multicenter cohort study

Published: 06-10-2022
Last updated: 25-09-2024

The aim of this study is to investigate the safety and efficacy of CAL-WR as primary and curative colon-preserving treatment for T1 colon cancer. Our primary endpoint is reduction of oncologic resections for low-risk T1 colon cancer. As secondary…

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Malignant and unspecified neoplasms gastrointestinal NEC
Study type	Observational invasive

Summary

ID

NL-OMON55909

Source
ToetsingOnline

Brief title
LIMERIC-II

Condition

- Malignant and unspecified neoplasms gastrointestinal NEC
- Gastrointestinal neoplasms malignant and unspecified

Synonym
T1 coloncarcinoma

Research involving
Human

Sponsors and support

Primary sponsor: Isala Klinieken
Source(s) of monetary or material Support: Isala Innovatie & Wetenschapsfonds

Intervention

Keyword: Early stage colon carcinoma, Local resection, T1 colon carcinoma, Wedge resection

Outcome measures

Primary outcome

Reduction of oncologic resections for low-risk T1 colon carcinomas by using

CAL-WR as primary treatment.

Secondary outcome

- Effectiveness (technically success and macroscopic- and microscopic R0

resection) of limited

treatment approach

- 3-year overall and disease free survival

- 5-year overall and disease free survival

- 30-day postoperative morbidity and mortality rate according to the

Clavien-Dindo classification I-V

- Total procedure related costs and cost effectiveness

- Postoperative quality of life

Study description

Background summary

The current standard oncological therapy for T1 colonic cancer is an oncologic resection with lymph node dissection. However, this therapy is associated with significant morbidity (24%) and mortality (2%). A significant part of the resected specimens (approximately 50%) shows no high-risk histological features for lymph node metastasis and therefore en-bloc local resection might be a valuable alternative. Recently we proved the Colonoscopic-Assisted Laparoscopic Wedge Resection (CAL-WR) to be a safe and effective technique to remove

endoscopic irresectable colonic lesions. We hypothesize that this local treatment approach can also be applied as initial treatment for T1-colon carcinoma and will be associated with less morbidity and mortality, better quality of life, less procedure related costs and similar survival compared with a standard oncological resection.

Study objective

The aim of this study is to investigate the safety and efficacy of CAL-WR as primary and curative colon-preserving treatment for T1 colon cancer. Our primary endpoint is reduction of oncologic resections for low-risk T1 colon cancer. As secondary endpoints, we will describe the effectiveness, morbidity, costs and oncological outcomes (recurrences, overall survival, and disease-free survival).

Study design

National prospective multicenter longitudinal cohort study

Study burden and risks

As we introduce here a minimal invasive local resection as primary treatment for T1 coloncarcinoma, we expect a significant part of the included patients (with a ''low-risk'' T1) to avoid a major oncologic resection and its associated high morbidity and mortality. Therefore, participants in this study will probably benefit directly from this investigation. Based upon our previous study (LIMERIC-(18)), we expect no major risks or complications to be associated with the procedure. The burden associated with participation in this study is limited to 3-times filling in two short questionnaires. There are no additional outpatient clinic visits or hospital admissions necessary for this study compared to current clinical practice.

Contacts

Public
Isala Klinieken

Dokter van Heesweg 2
Zwolle 8025 AB
NL
Scientific
Isala Klinieken

Dokter van Heesweg 2

Zwolle 8025 AB
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

• Lesion macroscopic suspect for T1 colon carcinoma during endoscopy (Hiroshima 2-3)
o Or histologically proven T1 colon carcinoma
• Size < 40mm
• Localized at least > 25cm proximal from the anus (measured endoscopically)
• > 18 years old

Exclusion criteria

• Rectal carcinoma
• Distant metastasis at baseline
• > 50% circumferential growth of the lesion
- Prior endoscopic resection or attempt, lifting not included

Study design

Design

Study type: Observational invasive
Masking: Open (masking not used)

Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	10-12-2022
Enrollment:	143
Type:	Actual

Ethics review

Approved WMO Date:	06-10-2022
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	03-11-2022
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	08-12-2022
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	12-04-2023
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	25-05-2023
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	26-09-2023
Application type:	Amendment

Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	17-07-2024
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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
CCMO	NL81497.075.22