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

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Ethical review	Approved WMO
Status	Recruitment started
Health condition type	Gastrointestinal therapeutic procedures
Study type	Observational non invasive

Summary

ID

NL-OMON55909

Source
ToetsingOnline

Brief title
LIMERIC-II

Condition

- Gastrointestinal therapeutic procedures

Synonym
T1 coloncarcinoma

Research involving
Human

Sponsors and support

Primary sponsor: Isala
Source(s) of monetary or material Support: Isala

Intervention

- Surigical procedure

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

Explanation

N.a.

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

Intervention

NA

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

Scientific
Isala
J. Hanevelt
Dokter van Heesweg 2
Zwolle 8025 AB
Netherlands
0637421727
Public
Isala

J. Hanevelt
Dokter van Heesweg 2
Zwolle 8025 AB
Netherlands
0637421727

Trial sites

Trial sites in the Netherlands

Bernhoven
Target size: 10

Amsterdam UMC
Target size: 5

Treant
Target size: 10

Ommelander Ziekenhuis Groningen
Target size: 5

Catharina-ziekenhuis
Target size: 10

Deventer Ziekenhuis
Target size: 10

Ziekenhuisvoorzieningen Gelderse Vallei
Target size: 10

Universitair Medisch Centrum Utrecht
Target size: 5

Isala
Target size: 60

IJssellandziekenhuis
Target size: 10

Jeroen Bosch Ziekenhuis
Target size: 10

Gelre Ziekenhuizen
Target size: 5

Maasstadziekenhuis
Target size: 5

Nij Smellinghe Ziekenhuis
Target size: 5

Elisabeth-Tweesteden ziekenhuis

Target size: 10

Meander Medisch Centrum
Target size: 10

Diakonessenhuis Utrecht
Target size: 10

Rivas Zorggroep
Target size: 10

Franciscus
Target size: 5

Rijnstate
Target size: 5

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 phase:	N/A
Study type:	Observational non invasive
Intervention model:	Single
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment started
Start date (anticipated):	10-12-2022
Enrollment:	144
Duration:	60 months (per patient)
Type:	Actual

Medical products/devices used

Product type:	N.a.

IPD sharing statement

Plan to share IPD: Undecided

Plan description
N.a.

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)
Approved WMO Date:	10-02-2025
Application type:	Amendment
Review commission:	METC UMCG

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
Research portal	NL-004930