Uniform Noting for International application of the Tumour-stroma ratio as Easy Diagnostic tool

No registrations found.

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

Summary

ID

NL-OMON23560

Source
Nationaal Trial Register

Brief title
UNITED

Health condition

colon cancer; staging, stroma, tumor-stroma ratio

Sponsors and support

Primary sponsor: Leiden University Medical Center (Leiden, the Netherlands)
Source(s) of monetary or material Support: Dutch Cancer Society (KWF)
Stichting Fonds Oncologie Holland (SFOH)

Intervention

Outcome measures

Primary outcome

1. Well trained (international) pathologists, having used the eLearning module, with low intra- and inter-observer variation.

2. Differences in Overall Survival (OS) and Disease Free Survival (DFS) between patients with a stroma-high tumour versus patients with a stroma-low tumour within each stage. Differences in response to current treatment regimens between patients with a stroma-high tumour versus patients with a stroma-low tumour.

Secondary outcome

3. A fully automated image analysis for the determination of the TSR.

4. A written proposal with guidelines for a clinical trial using shared-decision-making.

Study description

Background summary

There is increasing evidence that the tumour stroma plays an important role in the biological behavior of tumours, their growth, ability to metastasize, but also their response or resistance to anti-cancer drugs [1-4]. Tumours, that are rich in stroma behave in a more aggressive way compared to tumours that have little stroma.

The TSR parameter is based on the amount of stroma or fibrosis within the primary tumour and can be determined during routine pathology diagnostic assessment. Using the TSR, stage II/III stroma-high (high-risk) patients will be adequately registered for treatment with chemotherapy whereas for the (elderly) patient with stage III and stroma-low it can be further discussed if adjuvant therapy benefits. New guidelines for patient management will be developed and will have consequences for clinical patient management leading to a reduction in costs due to a better selection for adjuvant chemotherapy.

Study objective

The study goal is to add the TSR to current routine pathology diagnosis next to the TNM classification.

Study design

baseline / registration

surgery + pathology

3 year follow up for recurrence and survival

Intervention

Since the TSR is determined on routine resection tissue used for conventional pathological clinical decision making, there is no additional intervention for the patient.

Contacts

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Eligibility criteria

Inclusion criteria

histologically proven colon carcinoma

p-stage II or III

age ≥ 18 years

written informed consent

Exclusion criteria

neo-adjuvant treatment

no complete curative resection (not R0 resection)another malignancy within 10 years prior to the current colon carcinoma

multiple synchronous colon tumours

rectum tumours

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-07-2018
Enrollment:	1172
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	13-06-2018
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	NL7072
NTR-old	NTR7270
Other	CME LUMC : KWF 10174

Study results

Summary results
https://www.researchprotocols.org/2019/6/e13464/