A prospective study for the assessment of recurrence risk in stage II colon cancer patients using ColoPrint.

Published: 03-10-2008
Last updated: 06-05-2024

1. Organization and controlled implementation of ColoPrint® for prognosis prediction2. In stage II patients, prospective comparison of risk assessment by ColoPrint profile versus clinical parameters based on local protocol and ASCO high-risk...

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

Summary

ID

NL-OMON31942

Source
ToetsingOnline

Brief title
PARSC

Condition

- Malignant and unspecified neoplasms gastrointestinal NEC

Synonym
adenocarcinoma of the colon, colon cancer

Research involving
Human

Sponsors and support

Primary sponsor: Agendia B.V.
Source(s) of monetary or material Support: Agendia B.V.

Intervention

Keyword: colon cancer, molecular profiling, prospective, recurrence

Outcome measures

Primary outcome

• Endpoint: risk assessment by Physician (based on local protocol) in

comparison with ColoPrint result

• Endpoint: relapse or 3 years disease-free survival (DFS)

Secondary outcome

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Study description

Background summary

Despite numerous clinical trials, the benefit of adjuvant chemotherapy for stage II colon cancer patients is difficult to prove. Three-fourth of patients is cured by surgery alone and therefore, less than 25% of patients would benefit from additional chemotherapy. The identification of the sub-group of patients that are more likely to suffer from a recurrent disease would allow identifying those patients who should be treated after surgery. Current pathological prediction factors, most prominent staging, are not sufficient to identify *high risk* patients in either subgroup. For example, the finding that patients with stage IIB have a worse prognosis than patients with stage IIIA highlights the need to find better prognostic factors. Other clinical parameters like grade, number of assessed lymph nodes or vascular invasion are currently not used by all doctors in the same way. Additionally, the magnitude of risk conferred by these characteristics cannot be reliably estimated from available data.
Using microarray technology and tumor classification methods, a subset of genes was identified that are predictive for the prognosis of recurrence of stage II and III colon cancer (ColoPrint). In the training and validation set, the prognostic profile was more powerful than ASCO recommendations for selecting high risk stage II patients. Furthermore, mulitivariate analysis indicated that a combination of classifier and selected clinical variables could even more powerful and accurate in identifying high risk patients. A more detailed comparison between prognostic profile and clinical parameters should be

addressed in this study.

Study objective

1. Organization and controlled implementation of ColoPrint® for prognosis prediction
2. In stage II patients, prospective comparison of risk assessment by ColoPrint profile versus clinical parameters based on local protocol and ASCO high-risk recommendations which account for the presence of at least one of the following: T4, perforation/ obstruction, G3, and inadequate node sampling (less than 12 nodes).
3.Establishment of proportion *good prognosis profile* and *poor prognosis profile* in stage II and stage III colon cancer patients in various European countries
4. In stage III patients, exploratory analysis of the efficiency of ColoPrint in identifying low risk subgroups
5. Validation of the power of risk assessment

Study design

This study will address the logistic and quality assurance of using ColoPrint in clinical practice. The entire procedure of collecting and sending tissue samples, respective transfer of information, processing the tissue samples, carrying out diagnostic activities and reporting to the attending clinician must be set up at this stage (feasibility and implementation). In addition, risk assessment results from the prognostic profile (ColoPrint) will be compared to the risk assessment resulting from various clinical parameters following ASCO criteria and independent investigator risk assessment. The aim is to enroll maximal 600 stage II patients in order to compare the performance of ColoPrint against the clinical risk assessment in estimating 3 year relapse rate. The treatment of the patient is at the discretion of the physician.
Stage III patients will be analyzed on an exploratory basis. First 300 patients will not receive the study results. Second 300 patients will receive the study results.

Study burden and risks

After receipt of the results, the treatment of the patient is at the discretion of the physician. Patients will spend time reading the patient information and informed consent. The trial is not invasive. Patients will be asked permission for further use of their tumor tissue and sharing of clinical information with Agendia.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- > 18
- adenocarcinoma of the colon
- stage II (1-III) planned to be treated with radical surgery

Exclusion criteria

- prior malignancy with the exception of basal cell carcinoma or cervical dysplasia
- any neo-adjuvant therapy
- synchronous tumors

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-07-2008
Enrollment:	100
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Noord-Holland (Alkmaar)

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	NL23649.094.08