# Lateral Nodal Recurrence in Rectal Cancer

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| **Ethische beoordeling** | Niet van toepassing |
| **Status** | Werving nog niet gestart |
| **Type aandoening** | - |
| **Onderzoekstype** | Observationeel onderzoek, zonder invasieve metingen |

## Samenvatting

### ID

NL-OMON21039

**Bron**
NTR

**Verkorte titel**
LaNoReC

**Aandoening**

Rectal cancer

### Ondersteuning

**Primaire sponsor:** None
**Overige ondersteuning:** None

### Onderzoeksproduct en/of interventie

### Uitkomstmaten

**Primaire uitkomstmaten**

Lateral local recurrence

# Toelichting onderzoek

### Achtergrond van het onderzoek

Local recurrence rates in rectal cancer have reduced dramatically since the introduction of the total mesorectal excision (TME) technique. These rates have been lowered further with the use of neoadjuvant (chemo)radiotherapy ((C)RT) regimens in appropriate cases, decreasing overall rates of 5-year local recurrence to 5-10%. Western surgeons have always relied on (C)RT to sterilize the lateral compartment, containing the internal iliac and obturator lymph nodes, alleviating fears of operative morbidity and nerve function disorders associated with a lateral lymph node dissection (LLND), mainly performed in the East. Furthermore, most western clinicians consider lateral nodal disease to represent metastatic disease, not amendable to cure.

Recently, the lateral node study consortium undertook a multi-centre study with 12 centres from seven countries, collecting data over a 5-year period, including all consecutive patients operated for a cT3 or T4 rectal cancer. In all patients, every series of MRI's was re-reviewed by a standardized protocol, examining lateral pelvic nodes, defining these according to size and the presence of malignant features and relating these to the development of locally recurrent disease.
In the first publication of the consortium with a total of 1216 patients, it was shown that pre-treatment lateral lymph node (LLN) size of ≥7 mm, results in an unacceptably high incidence of lateral local recurrence of 19.5%, despite (C)RT with TME. Within the consortium, several centres performed LLND's after (C)RT, which resulted in a significantly lower rate of lateral local recurrence of 5.7% in nodes ≥7 mm ($p = 0.042$). Furthermore, LLN enlargement did not influence distant metastases rate, suggesting it is a local issue which requires to be addressed through targeted treatment in the pelvis, rather simply representing a marker of poor prognosis and distant disease.

To assess the value of restaging MRI, patients who underwent (C)RT and had a restaging MRI were then selected, leaving 741 for analyses: 651 had (C)RT+TME, 90 underwent (C)RT+TME+LLND. 96 patients (14.7%) had nodes ≥7 mm in short-axis on primary MRI (pre-SA). At 3 years after surgery, there were no lateral local recurrences in 28 patients (29.2%) with nodes that had a short-axis of ≤ 4 mm on restaging MRI (post-SA).
There was an important difference between the nodes located in the internal iliac compartment versus the ones in the obturator compartment. In the internal iliac nodes, there was only a 22% chance of becoming ≤ 4 mm. Pre-SA ≥ 7 mm, post-SA > 4 mm in the internal iliac compartment resulted in a 5-year lateral local recurrence rate of 52.3%. Adding LLND to (C)RT+TME in these malignant internal nodes, resulted in a significantly lower 8.7% lateral recurrence rate ($p = 0.0071$).
In the nodes in the obturator compartment, the chance of becoming ≤ 4 mm was 36%, but even in the nodes ≤ 6 mm (63%) there was a 0% chance of lateral local recurrence. If the nodes however remained post-SA > 6 mm, the chance of lateral local recurrence was 17.8%. This was reduced to 0% after a LLND.

The major drawback from this multi-center study is its retrospective nature, and although the

general guidelines of each center stated that in these types of rectal cancers would always have the lateral nodal compartments in the irradiation volume. However, whether they were always included for each individual patient and whether the node(s) were boosted was impossible to find out. It might be that the internal iliac were not always included in the irradiation volume, explaining the low response rate and the high lateral local recurrence rate.
Also, although it was reconstructed from the operation reports that all patients had a complete formal LLND, surgery was not standardized, not guaranteeing clearance of all nodes with formal anatomical landmarks and boundaries of the dissection.

The goal of this study is to raise national awareness in the Netherlands that even small lateral nodes (7mm) can cause lateral local recurrence if not treated adequately. The main question of this study is, whether after standardized and quality controlled irradiation of the lateral nodes and selective LLND performed in a tertiary referral center, the lateral local recurrence in rectal cancers with nodes with a short-axis of ≥ 7 mm can be reduced to below 6%.

### Doel van het onderzoek

The main question of this study is, whether after standardized and quality controlled irradiation of the lateral nodes and selective LLND performed in a tertiary referral center, the lateral local recurrence rate in rectal cancers with lateral nodes with a short-axis of ≥ 7 mm can be reduced to below 6%.

### Onderzoeksopzet

Normal follow-up until 3 years

## Contactpersonen

### Publiek

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### Wetenschappelijk

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# Deelname eisen

## Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

All patients with rectal cancer and one or more lateral nodes with a short-axis of ≥7mm. MR images are reviewed by a one of the study radiologists and both the nodes in the internal iliac as the obturator compartment are assessed. The largest node in each compartment is used as the reference short-axis in the flow charts. If there are both ≥7mm internal iliac and obturator nodes, the internal iliac flow-chart is used.

## Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Synchronous distant metastases
- Younger than 18 years old
- Other malignancies or pelvic irradiation in the medical history
- Medical conditions not able to take oral capecitabine
- Not fit for surgery

# Onderzoeksopzet

## Opzet

| | |
|---|---|
| Type: | Observationeel onderzoek, zonder invasieve metingen |
| Onderzoeksmodel: | Anders |
| Toewijzing: | N.v.t. / één studie arm |
| Blindering: | Open / niet geblindeerd |
| Controle: | N.v.t. / onbekend |

## Deelname

Nederland

| | |
|---|---|
| Status: | Werving nog niet gestart |
| (Verwachte) startdatum: | 01-10-2020 |
| Aantal proefpersonen: | 157 |

Type: Verwachte startdatum

### Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

**Wordt de data na het onderzoek gedeeld:** Nog niet bepaald

## Ethische beoordeling

Niet van toepassing
Soort: Niet van toepassing

## Registraties

### Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

### Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

### In overige registers

| Register | ID |
|---|---|
| NTR-new | NL8593 |
| Ander register | METc VUmc : 2020.098 / NL72626.029.20 |

## Resultaten