Detection of circulating tumour cells in cerebrospinal fluid (CSFCTs) to diagnose leptomeningeal metastases (LM) among breast cancer patients a pilot study

No registrations found.

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

Summary

ID

NL-OMON20288

Source Nationaal Trial Register

Health condition

Leptomeningeal metastases among breast cancer patients

Nederlands: Leptomeningeale metastasen bij patienten met mammacarcinoom.

Sponsors and support

Primary sponsor: Erasmus Medical Center Source(s) of monetary or material Support: Erasmus Medical Center

Intervention

Outcome measures

Primary outcome

1 - Detection of circulating tumour cells in cerebrospinal fluid (CSFCTs) to diagnos ... 16-06-2025

The detection rate of leptomeningeal metastases as the presence of at least 1 CSFCT in liquor (independent of volume) by the CellSearch method in patients with negative CSF cytology.

Secondary outcome

Molecular analysis of CSFCT and CTCs

Study description

Background summary

Currently available diagnostic techniques to diagnose LM are hampered by low sensitivity. In this pilot, we aim to improve the detection rate of LM in breast cancer patients by using the CellSearch technique, quantifying circulating tumor cells (CTCs) in cerebrospinal fluid and compare it with the current standard of care; i.e. cytopathological examination. We hypothyze that the detection rate of the CellSearch technique is higher compared to cytology.

Study objective

The detection rate of leptomeningeal metastases with the CellSearch technique is higher compared to cytology.

Study design

Additional liquor will be sent to the laboratory to detect and quantify tumor cells by the CellSearch technique.

Blood draw, preferably during a blood draw that was already necessary for standard care.

Intervention

Draw extra liquor for CSFCT during regular LP.

Contacts

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2 - Detection of circulating tumour cells in cerebrospinal fluid (CSFCTs) to diagnos ... 16-06-2025

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Eligibility criteria

Inclusion criteria

- Breast cancer patients with clinical suspicion of leptomeningeal metastases (LM) who are planned to undergo a lumbar puncture to confirm/exclude the diagnosis LM.

- Signed informed consent.

Exclusion criteria

- Contra-indication for lumbar puncture (on the discretion of the treating neurologist).

Study design

Design

Study type: Intervention model: Allocation: **Control:** N/A , unknown Observational non invasive Parallel Non controlled trial

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Recruitment

NL

3 - Detection of circulating tumour cells in cerebrospinal fluid (CSFCTs) to diagnos ... 16-06-2025

| Recruitment status: | Recruiting |
|---------------------------|-------------|
| Start date (anticipated): | 19-01-2016 |
| Enrollment: | 40 |
| Туре: | Anticipated |

Ethics review

Positive opinion Date: Application type:

12-01-2016 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 | NL5408 |
| NTR-old | NTR5533 |
| Other | : MEC15-419 |

Study results