# Caelyx PK.

No registrations found.

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

## Summary

### ID

NL-OMON23804

**Source**
NTR

**Brief title**
Caelyx-PK

**Health condition**

pharmacokinetics; caelyx; cancer

### Sponsors and support

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

### Intervention

### Outcome measures

#### Primary outcome

To assess age-related differences in PEG DOXO area under the curve (AUC) in elderly as compared to younger female cancer patients.

#### Secondary outcome

1. To assess age-related differences in PEG DOXO clearance (Cl) and terminal half life (T½z) in elderly as compared to younger female cancer patients;

2. To assess intra-patient variation of the AUC, Cl and T½ in both cohorts;

3. To assess age-related differences in toxicities associated with PEG DOXO in elderly as compared to younger female cancer patients;

4. To relate the toxicities associated with PEG DOXO to the PK data in both cohorts.

# Study description

### Background summary

Pharmacokinetic evaluation of the impact of age on the pharmacokinetics of caelyx.

### Study objective

Pharmacokinetics of caelyx may be altered in the elderly due to physiological changes.

### Study design

N/A

### Intervention

Pharmacokinetic sampling.

# Contacts

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# Eligibility criteria

## Inclusion criteria

1. Woman;

2. Solid tumour;

3. Under treatment with calyx;

4. Age 18 years or older.

## Exclusion criteria

1. Evidence of metastases in the central nervous system, unless previously treated and being asymptomatic/controlled for at least 3 months;

2. History of cardiac disease, with NYHA Class II or greater, or clinical evidence of congestive heart failure or myocardial infarction within less than six months;

3. Abuse of drugs, alcohol, pharmaceuticals, competing with adequate compliance in this study.

# Study design

## Design

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

## Recruitment

NL
Recruitment status: Recruiting

| | |
|---|---|
| Start date (anticipated): | 01-08-2008 |
| Enrollment: | 34 |
| Type: | Anticipated |

# Ethics review

| | |
|---|---|
| Positive opinion<br>Date: | 16-12-2010 |
| 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 | NL2540 |
| NTR-old | NTR2658 |
| Other | MEC Erasmus MC : 08-138 |
| ISRCTN | ISRCTN wordt niet meer aangevraagd. |

# Study results

**Summary results**
N/A