# The influence of hyperhydration on pemetrexed concetrations in blood.

No registrations found.

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

## Summary

### ID

NL-OMON21433

**Source**
Nationaal Trial Register

**Brief title**
HYDRA

**Health condition**

non-small cell lung cancer, NSCLC, mesothelioma

### Sponsors and support

**Primary sponsor:** ZANOB pharmacy/Jeroen Bosch Hospital
**Source(s) of monetary or material Support:** Self-financing research from ZANOB

### Intervention

### Outcome measures

**Primary outcome**

The primary endpoint is the observed difference in the pharmacokinetics of pemetrexed when administered with or without hyperhydration.

**Secondary outcome**

The secondary endpoint of our study is to screen whether novel renal function algorithms (CKD-EPI) outperform the classically used Cockroft-Gault algorithm to predict pemetrexed pharmacokinetics

# Study description

### Background summary

Pemetrexed is a pharmacotherapeutic cornerstone for treatment of non-small cell lung cancer and mesothelioma. Besides dose, renal function is the only determinant for systemic exposure: with decreasing renal function, systemic exposure increases accordingly. Since systemic exposure to pemetrexed (area under the concentration versus time curve (AUC)) is closely related with both efficacy measures (time to progressive disease) as (severe) toxicity, individualized dosing is of utmost importance to balance the dual risk of inefficacy and toxicity associated with treatment. We hypothesize that hyperhydration, which is given to promote excretion of cisplatin that is co-administered the first four cycles during combination therapy, causes augmented clearance of pemetrexed, resulting in decreased pemetrexed exposure. On the contrary, when in subsequent cycles cisplatin is not administered and hyperhydration is not performed, higher exposure and increased toxicity may be observed. Testing this hypothesis will further elucidate the pharmacokinetics of pemetrexed and may provide new insights regarding renal function as a determinant for optimal pemetrexed dosing and may be a next step to improved dosing with this cytotoxic agent.

### Study objective

Hyperhydration may cause augmented clearance of pemetrexed

### Study design

To obtain pharmacokinetic parameters and renal function parameters blood samples are drawn at set times during one cycle of combination therapy with hyperhydration and one cycle of monotherapy. To determine if there is a possible time- or sequence effect, five patients will be sampled at an extra cycle of monotherapy.

### Intervention

none

# Contacts

### Public

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# Eligibility criteria

## Inclusion criteria

1. At least 18 years old

2. Planned for treatment with cisplatin/pemetrexed combination therapy followed by pemetrexed maintenance therapy as a part of routine care.

3. Creatinine clearance ˃ 45ml/min

4. Subject is able and willing to sign the Informed Consent Form.

## Exclusion criteria

Patients that suffer from conditions that affect hemostasis in a way that blood drawing is complicated

# 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): | 01-03-2018 |
| Enrollment: | 15 |
| Type: | Anticipated |

# Ethics review

Positive opinion

| | |
|---|---|
| Date: | 06-03-2018 |
| Application type: | First submission |

# Study registrations

## Followed up by the following (possibly more current) registration

ID: 44619
Bron: ToetsingOnline
Titel:

## Other (possibly less up-to-date) registrations in this register

No registrations found.

## In other registers

| Register | ID |
|---|---|
| NTR-new | NL6889 |
| NTR-old | NTR7076 |
| CCMO | NL62137.028.17 |
| OMON | NL-OMON44619 |

# Study results