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# Metronomic chemotherapy with taxanes may reverse taxane resistance by anti-angiogenic effect

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| **Submission date**<br>18/08/2009 | **Recruitment status**<br>No longer recruiting | [_] Prospectively registered<br>[_] Protocol |
| **Registration date**<br>27/08/2009 | **Overall study status**<br>Completed | [_] Statistical analysis plan<br>[_] Results |
| **Last Edited**<br>27/08/2009 | **Condition category**<br>Cancer | [_] Individual participant data<br>[_] Record updated in last year |

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

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## Additional identifiers

**Protocol serial number**
RGZHSM 005

## Study information

**Scientific Title**
The combination of metronomic taxanes and valproic acid and enoxaparin decreases tumour marker levels in taxane refractory tumour types: a single arm, single centre, non-randomised, phase II feasibility trial

## Acronym
MTAX

## Study objectives
Metronomic chemotherapy with taxanes creates an important anti-angiogenic effect. This anti-angiogenic effect is enhanced by histone deacetylase inhibitors like valproic acid. The intracellular accumulation of chemotherapy is facilitated by enoxaparin.

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
Institutional Review Board of the Regionaal Ziekenhuis Sint Maria approved on the 7th April 2009

## Study design
Single arm single centre non-randomised phase II feasibility trial

## Primary study design
Interventional

## Study type(s)
Treatment

## Health condition(s) or problem(s) studied
Advanced solid tumours, metastatic disease

## Interventions
Patients will receive paclitaxel 20 mg/m^2/day on days 1 - 5 and 7 - 12 of a 21-day cycle. In patients with prior docetaxel exposure this becomes docetaxel 6 mg/m^2 on day 1 - 5 and 7 - 12 of a 21-day cycle. In both groups valproic acid 2 x 500 mg per day is added, and enoxaparin 40 mg is injected subcutaneously together with the chemotherapy.

Total duration of treatment: 6 months; follow-up duration: one year.

## Intervention Type
Drug

## Phase
Phase II

## Drug/device/biological/vaccine name(s)
Paclitaxel, docetaxel, valproic acid, enoxaparin

## Primary outcome(s)
Tumour marker decrease (carcinoembryonic antigen [CEA], prostate specific antigen [PSA], cancer antigen 15-3 [CA 15-3]) as a marker of the anti-angiogenic potential, after week 1, and thereafter every three weeks.

## Key secondary outcome(s))

Tumour response, assessed according to the Response Evaluation Criteria in Solid Tumors (RECIST), measured at week 19.

### Completion date
01/09/2010

## Eligibility

### Key inclusion criteria
1. Histologically or cytologically proven metastatic solid tumours. Patients must have disease which has failed standard taxane based chemotherapy.
2. Greater than or equal to 18 years of age, either sex
3. Eastern Cooperative Oncology Group performance status (ECOG PS) less than or equal to 3
4. Life expectancy greater than or equal to 8 weeks
5. Evaluable (based on radiological assessments or tumour markers) disease
6. Recovered (i.e., to National Cancer Institute [NCI] Common Terminology Criteria for Adverse Events [CTCAE] Version 3.0 Grade less than or equal to 1) from all toxicities associated with previous chemotherapy or radiotherapy (exception: patients may enter with continuing alopecia irrespective of CTCAE grade). The following intervals between starting last treatment must elapse:
6.1. Chemotherapy: at least 4 weeks
6.2. Mitomycin C or a nitrosourea: at least 6 weeks
6.3. Targeted therapy: at least 2 weeks or 2 half-lives, whichever is longer
6.4. Biologics: at least 4 weeks

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Adult

### Lower age limit
18 years

### Sex
All

### Key exclusion criteria
1. Pregnant women, women who are lactating, or women of childbearing potential who are not currently on effective means of birth control
2. History of QT/QTc prolongation, clinically significant ventricular tachycardia, ventricular fibrillation, heart block, myocardial infarction within 1 year, congestive heart failure New York Heart Association Class III or IV, unstable angina, angina within 6 months, or other evidence of clinically significant coronary artery disease
3. Active, ongoing infection, including viral hepatitis
4. Undergone major surgery within the last 4 weeks

5. Organ transplant recipients
6. New brain metastasis. Patients with treated (surgically excised or irradiated) and stable brain metastases are eligible as long as the treatment was at least 4 weeks prior to initiation of study drug and baseline brain computed tomography (CT) with contrast or magnetic resonance imaging (MRI) within 2 weeks of initiation of study drug is negative for new brain metastases.
7. Patients who have been on other experimental clinical trials of investigational agents within the last 28 days

**Date of first enrolment**
10/04/2009

**Date of final enrolment**
01/09/2010

# Locations

**Countries of recruitment**
Belgium

**Study participating centre**
**Ziekenhuislaan 100**
Halle
Belgium
1500

# Sponsor information

**Organisation**
St Mary Hospital (Sint-Maria Ziekenhuis) (Belgium)

# Funder(s)

**Funder type**
Industry

**Funder Name**
GEURS FILIP BVBA (Belgium)

# Results and Publications

## Individual participant data (IPD) sharing plan

### IPD sharing plan summary
Not provided at time of registration