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

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Non randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details provided in the interventions section to request a patient information sheet

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 measure
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.

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

Overall study start date
10/04/2009

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
24

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)

Sponsor details
c/o Mr Jan Claes
Directiesecretariaat
Ziekenhuislaan 100
Halle
Belgium
1500

Sponsor type
Hospital/treatment centre

Website
http://www.regzhsintmaria.be

Funder(s)

Funder type
Industry

Funder Name
GEURS FILIP BVBA (Belgium)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration