Mabtornib protocol. Vascular, metabolic and hormonal effects of angiogenesis inhibitors and EGFR inhibitors.

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Primary objective1.To determine the characteristics, frequency and severity of vascular, metabolic and hormonal side effects of angiogenesis inhibitors and EGFR inhibitors.Secondary objectives1.To investigate if steroid profile, indol profile,...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Endocrine and glandular disorders NEC
Study type	Observational non invasive

Summary

ID

NL-OMON33675

Source
ToetsingOnline

Brief title
Side effects of VEGF and EGFR directed therapy.

Condition

- Endocrine and glandular disorders NEC
- Bone, calcium, magnesium and phosphorus metabolism disorders
- Vascular hypertensive disorders

Synonym
Side effects

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: angiogenesis inhibitors, epidermal growth factor receptor, mTOR inhibitors, Side effects, tyrosine kinase inhibitors

Outcome measures

Primary outcome

Patients will be evaluated for vascular changes by measuring 24-hour ambulatory blood pressure, baroreflex sensitivity, nail fold capillary microscopy and arterial compliance measurement at 3 time points: before start of treatment, and after 3 and after 6 weeks of treatment. Patients will also be asked to measure their blood pressure at home twice a day, for 6 weeks. Metabolic and hormonal changes and investigation of biomarkers will be done by blood and urine analyses every 3 weeks for the first 3 months, every 6 weeks up to 6 months and every 3 months thereafter, and by skin autofluorescence before treatment and after 3 and after 6 weeks of treatment.

Changes in vascular, hormonal and metabolic status will be related to clinical side effects and to response to treatment.

Secondary outcome

When clinically relevant differences in side effects and response to treatment are found among patients treated with the same agent, DNA analysis will be carried out to investigate if changes in candidate genes are related to these differences.

Study description

Background summary

In recent years, multiple new agents have been developed that inhibit specific targets involved in cell growth, proliferation and angiogenesis, together called targeted therapy.
The cell signalling routes that are inhibited by these agents however, are not only active in cancer cells but are also involved in physiological processes in normal tissue and organs. This means that these drugs do not only have an anti tumour effect but also modify several physiological processes that lead to side effects. Little is known about these side effects that generally are less severe than side effects of cytotoxic chemotherapy, but because targeted therapy is often administered for prolonged periods of time, these side effects can seriously affect quality of life.

Study objective

Primary objective
1.To determine the characteristics, frequency and severity of vascular, metabolic and hormonal side effects of angiogenesis inhibitors and EGFR inhibitors.

Secondary objectives
1.To investigate if steroid profile, indol profile, concentrations of catecholamines and metanephrines or thyroid antibodies changes during treatment with angiogenesis inhibitors and EGFR inhibitors.
2. To investigation if known biomarkers change during treatment.
3. To investigate whether vascular function changes during treatment with angiogenesis inhibitors and EGFR inhibitors.
4. To determine if changes in skin autofluorescence and development of AGE*s occur during treatment with angiogenesis inhibitors and EGFR inhibitors.
5. To determine whether changes in factors mentioned under secondary objectives 1-4 are correlated with side effects of angiogenesis inhibitors and EGFR inhibitors and/or response to angiogenesis inhibitors and EGFR inhibitors.
6. To evaluate if polymorphisms in genes involved in pathways mentioned under 1-4 associate with toxicity and efficacy of angiogenesis inhibitors and EGFR inhibitors.

Study design

This is a prospective, explorational, observational cohort study.

Study burden and risks

The minimal invasive tests will be performed during routine outpatient visits. As far as known no serious adverse events are linked to described study procedures. With this study we hope to get insight into the characteristics, frequency, severity and underlying mechanisms of angiogenesis inhibitor and EGFR inhibitor induced vascular, metabolic and hormonal side effects and to find usable surrogate markers for efficacy of treatment. Eventually, this may contribute to the early detection of vascular, metabolic and hormonal changes, to the design of intervention strategies for side effects and to better patient selection for angiogenesis inhibitors and EGFR inhibitors .

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Patients treated with angiogenesis or EGFR inhibitors.
Concomitant chemotherapy, immunotherapy or radiotherapy is allowed.
- Age above 18 years at start of treatment
- Willingness to give written informed consent

Exclusion criteria

-Unable to give written informed consent
- Age under 18 years

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	25-03-2008
Enrollment:	240
Type:	Actual

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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
Other	2007/203
CCMO	NL18988.042.07