FASE II ONDERZOEK NAAR DE EFFECTIVITEIT VAN PAZOPANIB BIJ PATIËNTEN MET BAARMOEDERKANKER.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26478

Source
NTR

Brief title
PAZEC

Health condition

Metastatic or locally advanced endometrial cancer not amenable to other therapy

Sponsors and support

Primary sponsor: University Medical Center
Source(s) of monetary or material Support: GlaxoSmithKline BV the Netherlands

Intervention

Outcome measures

Primary outcome

Percentage of patients free of progression at 3 months.

Secondary outcome

1. Response rate;

2. Progression free survival;

3. Overall survival;

4. Tolerability/toxicity.

Study description

Background summary

This is a multicenter, open-label, non-randomized phase II study based on the optimal two-step Simon design. All eligible patients will be treated with pazopanib 800 mg PO daily until progression, unacceptable toxicity or patient refusal. After the end of study treatment, patients will be assessed for vital status every 3 months until death.

Study objective

Oral pazopanib once daily is safe and effective in advanced endometrial cancer for which no other therapies are available.

Study design

3 months for primary endpoint.

Until progression or death for other outcomes.

Intervention

Pazopanib 800 MG PO continuously until progression, unacceptable toxicity or patient refusal.

Contacts

Public
AMC
Dept Medical Oncology
A.M. Westermann
Meibergdreef

Amsterdam

The Netherlands
0031 (0)20 5669111
Scientific
AMC
Dept Medical Oncology
A.M. Westermann
Meibergdreef

Amsterdam
The Netherlands
0031 (0)20 5669111

Eligibility criteria

Inclusion criteria

1. Written informed consent;

2. Age ≥ 18 years;

3. Eastern Cooperative Oncology Group (ECOG) performance status of 0-2;

4. Histologically or cytologically confirmed diagnosis of endometrial cancer;

5. Metastatic disease or locally advanced tumor not amenable to local therapy;

6. Documented progressive disease before enrolment;

7. Measurable lesions outside irradiated field or progressive measurable lesions in irradiated area;

8. Not eligible for hormonal therapy (because of negative hormone receptor/poor differentiation,
or after failure of hormonal therapy);

9. Previous failure of chemotherapy, or refusal to undergo chemotherapy or chemo-naive patients not suitable for chemotherapy;

10. Adequate organ system function.

Exclusion criteria

1. Prior malignancy. Note: Subjects who have had another malignancy and have been disease-free for 5 years, or subjects with a history of completely resected non-melanomatous skin carcinoma or successfully treated in situ carcinoma are eligible;

2. History or clinical evidence of central nervous system (CNS) metastases or leptomeningeal carcinomatosis, except for individuals who have previously-treated CNS metastases, are asymptomatic, with no radiological signs of progression and have had no requirement for steroids or anti-seizure medication for 6 months prior to first dose of study drug;

3. Clinically significant gastrointestinal abnormalities that may increase the risk for gastrointestinal bleeding or may affect absorption of investigational product;

4. Presence of uncontrolled infection;

5. Corrected QT interval (QTc) > 480 msecs using Bazett’s formula;

6. History of major cardiovascular conditions within the past 6 months or poorly controlled hypertension, history of cerebrovascular accident including transient ischemic attack (TIA), pulmonary embolism or untreated deep venous thrombosis (DVT) within the past 6 months. Note: Subjects with recent DVT who have been treated with therapeutic anti-coagulating agents for at least 6 weeks are eligible;

7. Prior major surgery or trauma within 28 days prior to first dose of study drug and/or presence
of any non-healing wound, fracture, or ulcer (procedures such as catheter placement not considered to be major);

8. Evidence of active bleeding or bleeding diathesis;

9. Treatment with any of the following anti-cancer therapies: radiation therapy, surgery or tumor embolization within 14 days prior to the first dose of pazopanib OR chemotherapy, immunotherapy, biologic therapy, investigational therapy or hormonal therapy within 14 days or five half-lives of a drug (whichever is longer) prior to the first dose of pazopanib.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)

Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-11-2011
Enrollment:	55
Type:	Anticipated

Ethics review

Positive opinion

Date:	15-11-2011
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	NL2991
NTR-old	NTR3139
Other	METC AMC : 2011-000287-99
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A