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

Gepubliceerd: 15-11-2011 Laatst bijgewerkt: 18-08-2022

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

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON26478

Bron
NTR

Verkorte titel
PAZEC

Aandoening

Metastatic or locally advanced endometrial cancer not amenable to other therapy

Ondersteuning

Primaire sponsor: University Medical Center
Overige ondersteuning: GlaxoSmithKline BV the Netherlands

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Percentage of patients free of progression at 3 months.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

3 months for primary endpoint.

Until progression or death for other outcomes.

Onderzoeksproduct en/of interventie

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

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-11-2011
Aantal proefpersonen:	55
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	15-11-2011
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL2991
NTR-old	NTR3139
Ander register	METC AMC : 2011-000287-99
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten

N/A