Primair mamma en colon carcinoom: Is preeclampsie een onafhankelijke voorspellende marker voor risico stratificatie ?

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Hypothesis.In women with preeclampsia endovascular remodeling and invasion of the spiral arteries is less prominent which will result in overwhelming placental oxidative stress and pregnancy failure. Abnormal function of trophoblast and stroma cells...

Ethische beoordeling	Goedgekeurd WMO
Status	Werving gestopt
Type aandoening	Maagdarmstelselneoplasmata maligne en niet-gespecificeerd NEG
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON32468

Bron
ToetsingOnline

Verkorte titel
Primair mamma en colon carcinoom en preeclampsie e

Aandoening

- Maagdarmstelselneoplasmata maligne en niet-gespecificeerd NEG
- Borstneoplasmata maligne en niet-gespecificeerd (incl. tepel)
- Complicaties bij de moeder tijdens de zwangerschap

Synoniemen aandoening
Zwangerschapsvergifiting en kanker

Betreft onderzoek met
Mensen

Ondersteuning

Primaire sponsor: Medisch Centrum Haaglanden
Overige ondersteuning: Ministerie van OC&W

Onderzoeksproduct en/of interventie

Trefwoord: colon carcinoom, mammma carcinoom, preeclampsie, zwangerschap

Uitkomstmaten

Primaire uitkomstmaten

The stroma-percentage in colon and breast cancer with

- pregnancy outcomes: preeclampsia, intrautiene growth restriction

Secundaire uitkomstmaten

geen

Toelichting onderzoek

Achtergrond van het onderzoek

Colon and breast cancer are leading causes of cancer-related death in the Netherlands (10%, 2007 CBS stat line). Survival is directly related to detection and the type of cancer involved. However, tumor staging insufficiently discriminates between cancer patients with poor and better prognosis. Recently Mesker et al, described an independent parameter for survival using the stroma-percentage within the primary tumor of colon cancer patients. Patients with high stroma-percentage had a worse survival independent for either tumor stage, tumor status and lymph node status compared to patients with a high carcinoma-percentage. The stroma-percentage is available upon routine HE histological sections. (1,2) For breast cancer this parameter was validated on a set of 600 patients confirming the results of the former performed studies. (de Kruijf et al, submitted to JCO)

Pregnancy is also characterized by tumor invasion: adequate placenta invasion in the uterus is essential in pregnancy outcome.
In normal pregnancy spiral arteries undergo striking remodeling. They change from typical muscular arteries to flaccid tubes with no muscularis or elastic lamina with a diameter at least four times greater than that of non-pregnant vessels. Shortly after the invasion of trophoblasts into the superficial

endometrium, the maternal erythrocytes can be observed within the precursors of the placental intervillous space. Abnormal placentation is evident in preeclampsia. Preeclampsia is a pregnancy specific syndrome that is diagnosed by the new appearance of increased blood pressure and proteinuria. It is a leading cause of maternal mortality in developed countries and increases perinatal mortality up to five-fold. Since its etiology is largely unknown, panoply of pathophysiological abnormalities is described.
Intrauterine growth restriction results also in abnormal placental growth and angiogenesis with a prevalence of 5%.

Ten percent of the pregnant women will have problems with hypertension during pregnanacy, of which 3-7% will develop preeclampsia. Inclusion of women with intrauterine growth restriction will result in at least 5% of the total population of pregnant women to be involved with abnormal placental growth / angiogenesis.
Risk factors for abnormal placental growth / angiogenesis / preeclampsia are advanced maternal age during pregnancy, null parity, multiple gestation, diabetes, SLE and chronic hypertension. Smoking is a protective factor for preeclampsia, not for intrauterine growth restriction.

Doel van het onderzoek

Hypothesis.
In women with preeclampsia endovascular remodeling and invasion of the spiral arteries is less prominent which will result in overwhelming placental oxidative stress and pregnancy failure. Abnormal function of trophoblast and stroma cells and their interaction play an important role in abnormal placentation.
We hypothesize that preeclampsia during pregnancy is an independent, early clinical genetic marker of invasion for abnormal placental growth, pregnancy outcome including preeclampsia, intruterine growth restriction, abruptio placentae as well as cancer with high stroma formation (and thus worse prognosis).
The expected percentage of women in the population to be investigated would be 5% (12 patients with breast cancer and 17 patients with colon cancer) However, when a genetic predisposition is the cause of abnormal invasion this percentage is expected to be much higher in the series to be investigated.

Onderzoeksopzet

Methods.
For women with colon and breast cancer we will determine the stroma-percentage and gain insight in their pregnancy outcomes. Variables including tumor stage, tumor status and smoking will be analyzed in a regression analysis.
Abnormal trophoblast invasion is defined in preeclampsia as well as recurrent abortion, intra-uterine growth restriction and abrutio placentae.

Inschatting van belasting en risico

- We vragen de vrouwen een eenmalige vragenlijst over hun zwangerschap in te vullen.
- mogelijk is dat emotioneel voor vrouwen echter uit eerder onderzoek bij vrouwen met een ernstige preeclampsie en/of vroeggeboorte was dit geen probleem (Gaugler-Senden, paper submitted)

Contactpersonen

Publiek

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Wetenschappelijk

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Nederland

Locaties

Landen waar het onderzoek wordt uitgevoerd

Netherlands

Deelname eisen

Leeftijd
Volwassenen (18-64 jaar)
65 jaar en ouder

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Vrouwen met borst kanker en colon kanker behandeld in het LUMC

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

leeftijd < 18 jaar
indien bekend overleden

Onderzoeksopzet

Opzet

Type: Observationeel onderzoek, zonder invasieve metingen

Blindering:	Open / niet geblindeerd
Controle:	Geen controle groep
Doel:	Algemeen wetenschappelijk

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-07-2010
Aantal proefpersonen:	300
Type:	Werkelijke startdatum

Ethische beoordeling

Goedgekeurd WMO

Datum:	12-04-2010
Soort:	Eerste indiening
Toetsingscommissie:	METC Leids Universitair Medisch Centrum (Leiden)

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
CCMO	NL30048.058.09