Genomic and Epigenomic alterations after Cancer treatment In Pregnancy.

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To obtain a fundamental understanding if and which chemotherapeutic agents used for treating cancer during pregnancy are associated with offspring (epi)genetic changes, potentially causing FGR and childhood/adult diseases later in life.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Miscellaneous and site unspecified neoplasms malignant and unspecified
Study type	Observational invasive

Summary

ID

NL-OMON51958

Source
ToetsingOnline

Brief title
GE-CIP

Condition

- Miscellaneous and site unspecified neoplasms malignant and unspecified
- Neonatal and perinatal conditions

Synonym
chemo therapy, Pregnancy

Research involving
Human

Sponsors and support

Primary sponsor: UZ Leuven
Source(s) of monetary or material Support: Stichting tegen Kanker (subsidiegever België vergelijkbaar met KWF)

Intervention

Keyword: (epi)genomic, cancer, chemo therapy, pregnancy

Outcome measures

Primary outcome

determination of potential (sub)chromosomal alterations and/or changes in DNA methylation in cord blood and buccal cells of the newborn, and the association with chemotherapy concentrations measured in respectively placental or newborn tissue.

Secondary outcome

not applicable

Study description

Background summary

Cancer is the second leading cause of death during the reproductive years and affects between 1:1000 and 2000 pregnant women. Previous studies from our group have shown that chemotherapeutic cancer treatment in pregnancy has reassuring outcomes in terms of cognitive and cardiac neonatal outcomes, and hence has been proposed as standard of care [1-3]. However fetal growth restriction (FGR), which places an infant at significant risk of perinatal morbidity and mortality, is more common in women who were systemically treated during pregnancy compared to the non-cancer population. The possibility that chemotherapy during pregnancy causes placental (epi)genetic damage, and consequently induces FGR, or affects offspring DNA leading to potential deleterious effects later in life, such as cancer or other diseases, has not been investigated so far. As the cytotoxic effects of chemotherapy at DNA level have been well established, it could be speculated that chemotherapy-induced DNA damage may interfere with fetal and childhood health in the long term. The results of this study will lead to an increased understanding of potential toxic effects of chemotherapy for the unborn child and may therefore contribute to the development of safe and solid treatment regimens for pregnant cancer patients and their children.

Study objective

To obtain a fundamental understanding if and which chemotherapeutic agents used for treating cancer during pregnancy are associated with offspring (epi)genetic changes, potentially causing FGR and childhood/adult diseases later in life.

Study design

This international multicentre prospective observational trial functions as an extension of the CIP-study (Cancer in Pregnancy, S25470) and aims to collect placental tissue, cord blood and meconium and neonatal buccal cells at birth. Parental peripheral blood and buccal cells will be collected and used as reference. Minimal requirement to participate in this study is participation in CIP-study. Through this CIP-study we are able to gather pregnancy-, malignancy- and placenta-related data.

Study burden and risks

There are no risks associated with participation in this study.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

ancer in pregnancy - CT-treated arm (n=150)
• Histological proven cancer during pregnancy (any type and stage)
• (Former) participation in part I.IA of the CIP-study S25470 (and I.IB for the placental sub study)
• Treatment during pregnancy with one or a combination of the following chemotherapeutic agents:
- Cyclophosphamide
- Anthracyclines - Taxanes
- Platinum derivates
• Gestational age (GA) at birth >=24 weeks
Cancer in pregnancy - CT-untreated arm (n=150)
• No treatment during pregnancy or surgery only (subgroup 1)
• Radiotherapy and/or systemic treatment (other than CT) during pregnancy (subgroup 2)
• GA at birth >=24 weeks

Exclusion criteria

Exclusion criteria for the three study groups
• GA at birth <24 weeks (miscarriage or termination of pregnancy)
• Mentally disabled women or patients who have a significantly altered mental status that would prohibit the understanding and giving of informed consent
• Any comorbidity that is associated with an enhanced risk of placental pathology or FGR such as hypertensive disorders, preeclampsia, (gestational) diabetes, SLE, Crohn*s disease, renal or cardiac pathology (healthy pregnant controls)

Study design

Design

Study type:	Observational invasive
Intervention model:	Other

Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	13-06-2022
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO Date:	24-09-2021
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	30-11-2022
Application type:	Amendment
Review commission:	MEC Academisch Medisch Centrum (Amsterdam) Kamer G4-214 Postbus 22660 1100 DD Amsterdam 020 566 7389 mecamc@amsterdamumc.nl

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
CCMO	NL76873.018.21