DUTCH GOG
The Dutch Gynaecological Oncology Group

Application form DGOG STUDY

Title project	Cancer in Pregnancy (CIP-study)
Name and contact details of project leader	Prof. dr. Frédéric Amant UZ Leuven, Department of Gynaecological Oncology Herestraat 49 3000 Leuven, België Phone: +32 16 34 42 52 or Center of Gynecological Oncology Amsterdam, Location Amsterdam Universitary Medical Centers, Meibergdreef 9, 1105 AZ Amsterdam The Netherlands Phone: +31 20 512 29 75 E-mail: Frederic.amant@uzleuven.be
Background (Max 10 lines / 100 words)	Cancer is the second leading cause of death during the reproductive years in women and complicates between 1 in 1000-2000 pregnancies. In the past, physicians would prefer termination of pregnancy when diagnosed in the first trimester or start oncologic treatment after birth. However, pre-clinical data, case reports and small cohort studies have shown that oncologic treatment is in most cases possible during pregnancy, with re-assuring fetal outcome. Over the years more patients are initiating cancer treatment during pregnancy (ref. De Haan, Lancet, 2018). More research and evaluation of clinical practice is mandatory to guide physicians in decision-making.
Research question	**Part I Pregnancy, delivery and maternal health** Part I.I.A. Registration study 'Cancer during pregnancy' mother and neonate. *How are pregnant women diagnosed cancer (all types) managed during pregnancy? What is the obstetric, neonatal and oncological outcome?* Part I.I.B. Effects of prenatal exposure to cancer treatment on fetal growth. *What is the association between placental pathophysiologic mechanisms (histopathology and immunohistochemistry), circulating maternal factors and fetal growth?* Part I.II. Measurement of maternal and paternal anxiety and emotional needs when confronted with a cancer diagnosis during pregnancy Part I.III. Biobank 'cancer and pregnancy' *What are the clinicopathological, molecular and immunological characteristics of breast cancer during pregnancy and postnatal breast cancer?* Part I.IV. Study on the pharmacokinetics of chemotherapeutic agents in pregnant women **Part II Child** Long term follow up (physical examination by pediatrician, echocardiography if exposed to chemotherapy, neurocognitive testing, including Magnetic Resonance Imaging at the age of 9 years old (only in Leuven))) of children and adolescents in utero exposed to cancer or cancer treatment (surgery, chemotherapy, radiotherapy and/or target therapy). The children are tested at the age of 18 , 3 years, 6 years, 9 years, 12 years, 15 years and 18 years. After the age of 18 questionnaires are sent every 5 years.

Study design (Max 5 lines / 50 words)	International multicenter retrospective and prospective observational trial. Collection with informed consent of medical data for registration of cases, human tissue (placenta and breast cancer biopsies), psychological questionnaires and blood samples for pharmacokinetic analysis. Clinical and neurocognitive development of children is prospectively followed.
Power calculation (max 5 lines / 50 words)	International registration of cases is estimated to 150-200 cases yearly. For the placental analysis we aim to include 80 patients with cancer during pregnancy and 40 controls. For the follow-up of children a sample size calculation estimated 155 children per age group, based on 85% power analysis for intelligence testing.
National or intern. study? Cooperation with which groups ?	International study, in cooperation with 'The International Network on Cancer, Infertility and Pregnancy' (INCIP). Sponsor of the trial are the University Hospitals of Leuven, Belgium.Worldwide collaboration is utilized in order to include sufficient number of patients. Approval in 11 tertiairy hospitals in the Netherlands is obtained (by METC Erasmus Medical Center).
Funding	Both national, from Belgium and the Netherlands, and European grants are obtained for this project.
Estimated period of inclusion and area of inclusion.	Currently, we estimate the study to run until at least 2032. An updated list of participating sites per country can be found on: https://www.cancerinpregnancy.org/international-network