Nana Hyldig, MHSc, PhD student

Title: **Antibiotic Prophylaxis and Intervention for Postpartum Infections following Caesarean Section Forebyggelse og behandling af postoperative infektioner efter sectio**

This study is a multi-center study which consists of two sub-studies and a concurrent Health Economic Assessment. The overall study is designed to make a significant contribution to the research in prevention and treatment of postpartum infections following Caesarean Section.

Cohort 1
The aim is to examine, whether we by changing the time at which we give antibiotics during a caesarean section (before incision versus after the umbilical cord is clamped), can reduce the number postpartum infections following Caesarean Section. The study design will focus on the child's exposure to antibiotic prior to birth and infections occurred in the mother after discharge from hospital. We expect to include 2844 women over a 2-year period.
In order to identify infections in the mother after discharge, all participants will receive a questionnaire a month after birth. The questionnaire collects self-reported data on infection and quality of life. Data from the questionnaire will be linked to data from various central registers. Faeces samples will be collected immediately after birth and again 3-6 month after birth. Furthermore we plan to do a follow-up on the children at the age of five.

Hypoteses:

- Antibiotics administered before caesarean section will lead to 30 % less postpartum infections than antibiotics administered during caesarean section, after the umbilical cord is clamped.
- There is no difference in the number of children admitted to hospital relative to which time antibiotics is administered during birth.
- Antibiotics administered before caesarean section is cost-beneficial compared to antibiotics administered after the umbilical cord is clamped.

Cohort 2
The aim is to examine whether Negative Pressure Wound Therapy (NPWT) is an efficient wound treatment compared to conventional treatment for wound infections for women, whom are re-admitted for re-operation due to an infection or a hematoma in the operation wound after caesarean section. We expect to include 50 patients over a 2-year period.

Hospitalization, time-period until 100 % healing and resource consumption is registered and the cosmetic outcome is evaluated at 6 and 12 month controls. The given treatment's effect on the patient's quality of life is also evaluated.

Hypoteses:

- NPWT lead to less cases of re-rupture than conventional wound treatment.
- NPWT gives a better cosmetic result than conventional wound treatment.
- NPWT is cost-beneficial compared to conventional wound treatment.

Data will be obtained from: The Danish National Patient Registry, The Danish Medical Birth Registry, The Odense University Pharmacoepidemiological Database (OPED), medical journals, registration forms, electronic patient questionnaires and photos of the section scar after reoperation.

Principal supervisor: Consultant, Chief Obstetrician Associate Professor MD, PhD Jan Stener Jørgensen, Department of Gynaecology and Obstetrics, Odense University Hospital.

Supervisor: MD, PhD Camilla Bille, Department of Plastic Surgery, Odense University Hospital.

Supervisor: BSc MB ChB MD FRCOG, Consultant Obstetrician & Gynaecologist, Professor and Reader Ronald F Lamont, Division of Surgery, Northwick Park Institute of Medical Research, University College London, UK and University of Southern Denmark.

Supervisor: Research Associate, MSc(Economics), PhD Marie Kruse, Danish Institute for Health Services Research, Copenhagen.

Co-partners:

MD, PhD Anette Holm, Department of Clinical Microbiology, Odense University Hospital

Clinical Professor, Chief Physician, MD. Gorm Greisen, The Neonatal clinic at the Juliane Marie Center, Rigshospitalet

Chief Obstetrician, MD Tom Weber, Department of Gynaecology and Obstetrics, Hvidovre Hospital

Chief Consultant, MD Jane Maria Lyngsø, Department of Gynaecology and Obstetrics, Hospital South West Jutland, Esbjerg

The GCP unit, Odense University Hospital, Department of Clinical Chemistry and Pharmacology

Odense Patient data Explorative Network, Department of Clinical Immunology, Odense University Hospital

Odense PharmacoEpidemiological Database, Clinical Pharmacology, University of Southern Denmark