Assessing risk perception of anti-emetic drug use during pregnancy and the potential impact of risk communication tools: A study protocol

Fergal O'Shaughnessy[1, 2], Jennifer Donnelly[3,4], Nicola Maher[3,4], Meena Ramphul[3,4], Brian Cleary[1,2]

[1]Pharmacy Department, Rotunda Hospital. [2] School of Pharmacy and Biomolecular Science, Royal College of Surgeons in Ireland. [3] Department of Obstetrics and Gynaecology, Rotunda Hospital. [4] Department of Obstetrics and Gynaecology, Royal College of Surgeons in Ireland.

Background

Many international guidelines recommend pharmacological treatment in the management of nausea and vomiting in pregnancy (NVP). It has been estimated that half of all women in the UK with a diagnosis of NVP were prescribed antiemetic therapy.

The potential risks of antiemetic exposure during pregnancy should be balanced with the benefits of managing a severe underlying maternal condition that can lead to adverse pregnancy outcomes.

Recently the European Medicines Agency's Pharmacovigilance Risk Assessment Committee (EMA-PRAC) has recommended against the use of ondansetron in the first trimester. There are concerns within the European Network of Teratology Information Services (ENTIS) that currently available data do not support the recommendations against ondansetron in the first trimester, and that this may lead to less effective control NVP and increased morbidity; instead, women should be counselled on the benefits and risks of antiemetic therapy to allow individualized decision making.

Aim

The aim of this study is to explore the perception of risk associated with antiemetic drug use during pregnancy and the potential impact of risk communication tools on individualized decision making.

Study protocol

Population: Women who are currently pregnant or who have been pregnant within the last 3 years

Intervention: Novel risk communication formats

Comparison: Traditional risk communication formats

Outcome: Measures of realistic expectation, choice predisposition, knowledge, decision making

Distribution methodology: Online and social media channels

Methods

A web-based questionnaire has been developed to explore the potential impact of novel risk communication tools on individualized decision making in the context of medication use for NVP.

1 Recruitment

Women will be recruited and consented through social media channels and patient support groups.

2 Randomisation

Women will be randomized to receive one of three locally developed risk communication tools

3 Risk communication

The risk communication tools will present the benefits and risks of ondansetron use in pregnancy using different narrative and visual risk communication techniques

4 Assessment

The utility of different risk communication methods will be assessed by measuring:

- Realistic expectation
- Choice predisposition
- Knowledge
- Preparation for decision making

5 Analysis

- Does the risk communication method influence a woman's decision to take medication during pregnancy
- Do women have a preference as to the format of risk communication tools?

Results

Results expected Q1 2021