

Pregnancy register for women who have had children whilst on modified release subcutaneous buprenorphine formulations

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Introduction

Buprenorphine (BPN) is a first line treatment (alongside methadone) for opioid dependence in pregnancy with the potential for a less severe neonatal opioid withdrawal syndrome.

Despite scarce data on the safety and effectiveness of depot BPN formulations in pregnancy and breastfeeding (n= 3 in the peer reviewed literature), clinical cases highlighting its safety and potential advantages over other opioid agonist treatment options have been reported. Our group is aware of 6 cases to date of use of depot BPN in pregnancy in NSW without adverse outcome. In NSW, depot guidelines advise a risk-benefit assessment of depot BPN treatment during pregnancy. A current RCT in USA (the "Moms' study) aims to compare mother and infant outcomes of pregnant women with opioid use disorder treated with depot BPN, relative to sublingual BPN is underway.

Method / Approach: We will report on the development of a national register of pregnancies where women were treated with depot BPN during pregnancy and collect data on maternal outcomes (gestation, adverse events), neonatal outcomes (birthweight, head circumference, neonatal opioid withdrawal, adverse events) by collecting retrospective and prospective de-identified data. The aim for this register is to provide publicly available information of the safety of depot BPN in pregnancy in Australia.

Key Findings: Whilst awaiting the results of controlled studies internationally, a local pregnancy register will be an important data source on the safety of depot BPN during pregnancy for practitioners and patients.

Discussions and Conclusions: Product information for all formulations of subcutaneous long acting depot BPN and local clinical guidelines suggest a risk-benefit assessment of continuing depot BPN during pregnancy.

Implications for Practice or Policy (optional): Clinicians and patients will benefit from additional local data on the maternal and neonatal safety during pregnancy of depot BPN formulations facilitating choice in healthcare and use of safe medicines.

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