fatal consequences. Missing dependent and independent controls regarding concentration and identity pose a risk for patient safety.

Purpose We developed a concept for a two-stage quality control of the infusion solutions. Drug identity and concentration can be checked onsite after preparation using a combined UV- and Raman spectrometer (UV-Raman). This is complemented by an independent method using liquid chromatography coupled to UV detection (HPLC-UV).

Material and methods Methods for the analysis of seven cytostatic drugs and two monoclonal antibodies were developed and validated on an i-QCRx UV-Raman system (B and W Tek Europe GmbH, Lübeck, Germany) and on an Agilent 1200 series HPLC-UV system (Agilent Technologies, Waldbronn, Germany). Sample transport and preparation were evaluated to ensure valid results. In a pilot study we analysed samples from different pharmacies in both systems.

Results Method development and validation were successful for the investigated compounds in both systems. HPLC-UV is more sensitive than UV-Raman. However, due to the content of the preparations, real samples had to be diluted before applying HPLC-UV analysis. Sensitivity of the UV-Raman spectrometer fits to the required concentration range without further dilution. All methods showed reproducible results, UV-Raman varied by 0.44% in a repeated analysis (n=3) of 5-fluorouracil, while HPLC-UV varied by 0.14%. Results of the investigated samples were also equivalent. In a sample containing paclitaxel with a target concentration of 0.72 mg/mL we determined 0.73 mg/mL (101%) using UV-Raman and 0.69 mg/mL (96%) using HPLC-UV, for example.

Conclusion UV-Raman and HPLC-UV are suitable for determining the content of patient-individual preparations, both with individual assets and drawbacks. The study showed that the two-stage control concept is appropriate to ensure a high-quality level for patient-individual preparations.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

Section 6: Education and Research

6ER-001 HIGH VERSUS LOW DOSE OF URSODEOXYCHOLIC ACID FOR THE MANAGEMENT OF INTRAHEPATIC CHOLESTASIS OF PREGNANCY: A COHORT RETROSPECTIVE STUDY OF MATERNAL AND NEONATAL OUTCOMES

¹R Barazi*, ²O Alkhazondar, ¹A Kilani, ³S Kassim, ⁴E Mohamed, ⁵G La Monica, ¹E Alhamoud, ¹R Elenany, ³M Alloub. ¹Hamad Medical Corporation, Pharmacy, Al Wakra, Qatar; ²Hamad Medical Corporation, Pharmacy, Wakra, Qatar; ³Hamad Medical Corporation, Ob/Gyn, Al Wakra, Qatar; ⁴Hamad Medical Corporation, Pharmacy, Doha, Qatar; ⁵Sidra Medicine, Ob/Gyn, Doha, Qatar

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Background Intrahepatic cholestasis of pregnancy (ICP) is a pregnancy-related reversible hepatic disease. The clinical importance of ICP lies in neonatal and maternal ICP-associated complications which include higher rates of perinatal morbidity and mortality, increased rates of caesarean sections, increased risk of meconium staining of amniotic fluid, preterm delivery, fetal bradycardia, fetal distress and fetal demise. The underlying mechanisms associated with poor

neonatal outcome have been shown to be associated with elevated maternal total serum bile acids (40 mmol/L) antenatally.

Ursodeoxycholic acid (UDCA) has shown to result in a significant improvement in symptomatic relief, biochemical markers and gestational age of delivery in patients with ICP. However, a consensus is lacking for the optimal UDCA dosing regimen.

Purpose The study is primarily to compare the effect of a high versus low dose of ursodeoxycholic acid in maternal and neonatal outcomes. This study will also determine the characteristics associated with ICP in a cohort of patients.

Material and methods Design: Retrospective cohort study as ICP is a rarely occurring hepatic disease.

Setting: Most ICP patients get diagnosed or referred to governmental hospitals located in their area of residence for inpatient and outpatient care.

Participants: ICP patients who underwent management of their disease in Ob/Gyn units between July 2016 and July 2017. Patients were identified using institutional medical records.

Main outcome measures: Maternal outcomes: Mode of delivery, gestational age at diagnosis and gestational age at delivery. Neonatal outcomes: APGAR score: 1 min, 5 min and 15 min; birthweight in g and NICU admission.

Results None of the patients had a history or concurrent diagnosis of other hepatic or biliary disease. A small proportion of both the high-dose and low-dose study population had histories of ICP in previous pregnancies: three in the high-dose group and two in the low-dose group. The mean bile acid level upon diagnosis was 19.7 mmol/L in the high-dose group paralleled to 17 mmol/L in the low-dose group. Other neonatal and maternal outcomes will be presented in the poster.

Conclusion This study failed to detect or prove the difference in the maternal and neonatal clinical outcomes between the UDCA high- and low-dose groups.

REFERENCES AND/OR ACKNOWLEDGEMENTS

<https://www.ncbi.nlm.nih.gov/pubmed/24901263>[https://www.jogc.com/article/S1701-2163\(15\)30544-2/pdf](https://www.jogc.com/article/S1701-2163(15)30544-2/pdf)

No conflict of interest.

6ER-002 EFFICACY OF A FIXED-RATIO COMBINATION OF INSULIN DEGLUCED AND LIRAGLUTIDE IN THE TREATMENT OF TYPE 2 DIABETES MELLITUS

¹V Ožana*, ²M Frydrych. ¹Hospital with Polyclinic Karvina-Raj- Orlova City Branch, Pharmacy, Orlova, Czech Republic; ²University of Veterinary and Pharmaceutical Sciences Brno, Department of Human Pharmacology and Toxicology- Faculty of Pharmacy, Brno, Czech Republic

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Background Based on the current recommendations, a fixed-ratio combination of insulin degludec and GLP-1 agonist liraglutide (IDegLira) is considered to be an equivalent alternative to an intensified insulin regimen for type 2 diabetes mellitus (T2DM). As a once-daily injection with effects on both fasting and postprandial hyperglycaemia, IDegLira provides, according to several studies, optimal glycemic and metabolic control.

Purpose To determine the effectiveness of IDegLira in the reduction of glycemic parameters, bodyweight and lipid profile parameters in patients with a diagnosis of T2DM.