

therapies, a close patient guidance and management is essential to prevent treatment failure because of drug-drug or drug-food interactions, side effects or non-adherence.

Aim and objectives The aim of this study is to investigate whether integrating a clinical pharmacist/clinical pharmacologist into a multi-professional care team can improve patients' safety, knowledge and well-being.

Materials and methods For this purpose, 200 patients will be randomised. While the intervention group will receive an intensive care program with information material and side effect management, the control group will only receive routine clinical care. Primary outcome parameters are the number of drug related problems (medication errors and side effects) regarding the oral anticancer drug and patient satisfaction (TSQM questionnaire). Further outcome parameters will include, for example, the number of serious side effects and hospitalisation rates.

Results For this interim analysis, 100 patients were included. In the intervention group the number of drug related problems regarding the oral anticancer treatment was reduced (7.38 vs. 4.75 per patient; $p < 0.05$) and patient satisfaction was significantly increased ($p < 0.01$). The intervention group showed a lower rate of serious side effects and was less frequently admitted to a hospital.

Conclusion and relevance The high rate of drug related problems in this patient population indicates that cancer patients treated with oral anticancer drugs must be considered as a high-risk patient group. Early intervention can reduce serious side effects and increases patients' satisfaction. The integration of a clinical pharmacist/clinical pharmacologist in a multi-professional care team increases medication safety in patients treated with oral anticancer drugs.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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NP-003

STEADY-STATE PHARMACOKINETICS AND EARLY SAFETY DATA IN HIV-INFECTED AFRICAN CHILDREN WEIGHING ≥ 25 KG AFTER SWITCHING TO 50 MG FILM-COATED DOLUTEGRAVIR TABLETS IN THE ODYSSEY TRIAL

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Background and importance ODYSSEY is an ongoing international randomised trial evaluating dolutegravir (DTG)-based antiretroviral therapy (ART) versus standard-of-care in HIV-infected children starting first- or second-line ART. Pediatric DTG film-coated tablets (FCTs) of 10 mg and 25 mg are unavailable in low- and middle income countries (LMIC) were most HIV-infected children live. Adult DTG 50mg FCTs are produced by generic manufacturers at low-cost, are well-tolerated, and already available in many high- and LMICs.

Aim and objectives Within ODYSSEY pharmacokinetic (PK) substudies were undertaken to assess PK and safety data for a simplified paediatric DTG dosing approach using WHO weight bands (WBs) 25 to <30 kg and 30 to <40 kg and once daily 50 mg adult DTG doses.

Materials and methods Steady-state 24-hour PK curves were constructed from data in children (≥ 3 h fasted) observed taking current EMA-approved DTG doses of 25 mg and 35 mg (10 mg+25 mg FCTs) in 25- <30 kg and 30- <40 kg WBs, respectively. After all children switched to single daily 50 mg DTG tablet, a second 24 h PK curve was constructed. We aimed to achieve DTG exposures comparable to historical adult data for DTG 50 mg FCTs QD taken under fasted conditions (geometric mean (GM): C_{trough} 0.83 mg/L, AUC_{0-24h} 43.4 h*mg/L, C_{max} 3.34 mg/L). Additionally, results were compared to PK data for DTG 50mg BID in adults (GM ranges: C_{trough} 2.41 to 2.72 mg/L, AUC_{0-24h} 93.4 to 92.7 h*mg/L, C_{max} 5.41 to 5.55 mg/L). Safety was evaluated after switch to the 50mg dose at 2, 4 and 12 weeks and then every 12 weeks.

Results 28 black-African children (52 PK profiles) from Uganda and Zimbabwe (61% male) with a median (range) age of 11.0(7.5–17.9) years old were included. For children weighing 25- <30 kg on DTG 25 mg (17 profiles) GM with coefficient of variation (CV%) for C_{trough} and AUC_{0-24h} was 0.39(48) mg/L and 33.1(23) h*mg/L, respectively, and after switch to DTG 50 mg (16 profiles) values were 0.77(43) mg/L and 58.6(28) h*mg/L, respectively. For children weighing 30- <40 kg on DTG 35 mg (9 profiles), C_{trough} and AUC_{0-24h} were 0.46(63) mg/L and 40.3(35) h*mg/L, and after switch to DTG 50 mg (10 profiles) values 0.63(49) mg/L and 53.5(32) h*mg/L, respectively. The 50 mg dose resulted in C_{max} values of 5.41(25) mg/L and 5.22(25) mg/L in WB 25- <30 kg and 30- <40 kg, respectively, which did not exceed historical C_{max} values for adults on 50 mg BID. After a median (IQR) follow-up of 30(12–30) weeks on 50 mg DTG 3/28(11%) children had grade 3 or 4 adverse events (one SAE; cryptococcal meningitis) and all were considered unrelated to DTG.

Conclusions and relevance Adult 50 mg FCT once-daily dolutegravir provides appropriate PK profiles in children ≥ 25 kg, with no safety signal, allowing practical dosing and rapid access to dolutegravir. WHO has released new pediatric dosing guidelines in response to these results.

NP-004

INITIATION OF A CLINICAL PHARMACIST LED, PROSPECTIVE AUDIT ON ANTIBIOTIC PRESCRIBING

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Background and importance A pharmacist led, prospective audit on antibiotic prescribing was introduced on three hospital wards, as an element of the local, institutional antibiotic stewardship program (ASP).

Aim and objectives Our aims were to document and evaluate each antibiotic prescription and therapy based on the antimicrobial stewardship program recommendations and to give feedback to prescribers on their compliance to ASP guidelines.

Material and methods A paper-based audit form was prepared. Patient data, documentation of allergies, indication of the therapy and circumstances of microbiological testing were