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Developing a Nationwide Infrastructure for Therapeutic Drug Monitoring of Targeted Oral Anticancer Drugs: The ON-TARGET Study Protocol

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Exposure-efficacy and/or exposure-toxicity relationships have been identified for up to 80% of oral anticancer drugs (OADs). Usually, OADs are administered at fixed doses despite their high interindividual pharmacokinetic variability resulting in large differences in drug exposure. Consequently, a substantial proportion of patients receive a suboptimal dose. Therapeutic Drug Monitoring (TDM), i.e., dosing based on measured drug concentrations, may be used to improve treatment outcomes. The prospective, multicenter, non-interventional ON-TARGET study (DRKS00025325) aims to investigate the potential of routine TDM to reduce adverse drug reactions in renal cell carcinoma patients receiving axitinib or cabozantinib. Furthermore, the feasibility of using volumetric absorptive microsampling (VAMS), a minimally invasive and easy to handle blood sampling technique, for sample collection is examined. During routine visits, blood samples are collected and sent to bioanalytical laboratories. Venous and VAMS blood samples are collected in the first study phase to facilitate home-based capillary blood sampling in the second study phase. Within one week, the drug plasma concentrations are measured, interpreted, and reported back to the physician. Patients report their drug intake and toxicity using PRO-CTCAE-based questionnaires in dedicated diaries. Ultimately, the ON-TARGET study aims to develop a nationwide infrastructure for TDM for oral anticancer drugs.

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