

Summary Attachment – EudraCT

We initially aimed to investigate the concentrations of both cefuroxime and piperacillin in bile and plasma in patients undergoing endoscopic retrograde cholangiopancreatography (ERCP), a procedure commonly referred to as an endoscopic examination of the bile ducts.

Due to a longer-than-anticipated inclusion period, we decided to focus solely on piperacillin and refrained from measuring cefuroxime concentrations.

A total of 100 patients were enrolled in the study. However, one patient had to be excluded due to a missing blood sample, which was only discovered after the inclusion period had ended.

As each patient contributed only one bile and one plasma sample, and due to the heterogeneity of the patient population, it was not feasible to assess pharmacokinetic parameters or time above the minimum inhibitory concentration ($T > MIC$). Consequently, the study was conducted as a descriptive analysis.

We observed a general trend indicating that piperacillin concentrations were markedly higher in bile compared to plasma. Exceptions to this pattern were noted in a subset of patients who either had their samples collected within the first 75 minutes following drug administration or had experienced prolonged biliary obstruction, such as in cases of malignancy.

On behalf of the sponsor,

Louise Lerche Pontoppidan, MD

Department of Surgery, Lillebaelt Hospital

University Hospital of Southern Denmark