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7th World Congress on

Bioavailability & Bioequivalence: BA/BE Studies Summit

August 29-31, 2016 Atlanta, USA

Prasugrel effect on *in vitro* bleeding time tests in a single dose bioequivalence study

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Prasugrel co-administered with acetylsalicylic acid is indicated for the prevention of atherothrombotic events in adult patients with acute coronary syndrome undergoing primary or delayed percutaneous coronary intervention. Prasugrel is a prodrug. It is rapidly absorbed after oral doses and undergoes hydrolysis in the intestine before being metabolized by several cytochrome P450 isoenzymes to the active metabolite. Binding of the active metabolite to human serum albumin is about 98%. The active metabolite is further metabolized to two inactive compounds which are excreted in the urine and feces; about 68% of a dose is excreted in urine and about 27% in faeces. The elimination half-life of the active metabolite is about 7.4 hours. Our study is comparative bioavailability study of prasugrel after single dose administration (fasting and fed conditions) of prasugrel 10 mg film-coated tablets (Test product) and Effient® 10 mg Filmtabletten (Reference product) in healthy male subjects. In this study, *in vitro* bleeding time tests (Collagen ADP and Epinephrine) were performed during first and final laboratory examinations. PFA 100 P2Y kit was used for the measurement of this test. When used in the treatment of prasugrel it was expected to extend *in vitro* bleeding time test. But, in our study, *in vitro* bleeding time or remained unchanged or decreased in the first and final laboratory examinations. Consequently, there is no need for bleeding time tests in a single dose bioequivalence study.

Biography

Ahmet Inal has completed his PhD in Pharmacology from Erciyes University and Post-doctoral studies from Erciyes University, School of Medicine. He is the Principle Investigator of Hakan Çetinsaya Good Clinical Practice and Research Center. He is an Assistant Professor at Erciyes University, School of Medicine. He has worked on more than 800 bioequivalence studies.

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