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Overview of bioavailability/bioequivalence clinical trials in a phase 1 in Turkey

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Multisource pharmaceutical products need to conform to the same standards of quality, efficacy and safety as required of the originator's product. Testing the bioequivalence between a product and a reference in a pharmacokinetic study with a limited number of subjects is one way of demonstrating therapeutic equivalence. Bioavailability/bioequivalence (BA/BE) trials have been conducted in our clinic, Turkey, since 2000. We have collaborations with several companies from foreign countries. We want to evaluate the phase 1 trials which were carried in our clinic between the years 2005 and 2015. The distribution of these 947 trials according to years was as follows: 151 in 2005, 118 in 2006, 123 in 2007, 120 in 2008, 88 in 2009, 84 in 2010, 68 in 2011, 51 in 2012, 54 in 2013, 36 in 2014 and 54 in 2015. If we group these trials, we can see that the largest group is antibiotics. Furthermore, the antihypertensive medicines, anti-seizures, antipsychotics, anti-depressants, analgesic medicines, peptic ulcer medicines, anti-diabetic medicines, antihyperlipidemic medicines and the rest consists of the other groups. The number of trials and medicine groups which were studied in our clinic, change according to years. For example number of BA/BE trials related antibiotics are less than previous years. As a result BA/BE trials are improving in Turkey. They are conducting according to Turkish Regulations Regarding Clinical Trials of Drugs and Biologics which is similar to EMEA and FDA regulations.

Biography

Zafer Sezer was graduated from Istanbul University, Cerrahpaşa Medical Faculty as a Medical Doctor in the year 1999. He has completed his Post-doctoral research in Pharmacology Department of Erciyes University, School of Medicine. He has been working as a Principal Investigator in Hakan Çetinsaya GCP and Research Center since 2008. Additionally, he is a Member of Erciyes University Clinical Researches Ethical Committee.

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