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Some aspects of clinical endpoint bioequivalence studies

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Bioequivalence clinical trials aim to investigate the bioavailability of the compared drugs in the human body. The credibility and clinical value of this approach is arguable among clinicians whose interest is lying beyond the peculiarities of pharmacokinetics of the certain drug in healthy organism. The endpoint for clinical physicians is accomplished when the significant therapeutical effect of the drug is induced in patients with a common disease or state. For this reason, clinicians tend to prefer clinical endpoint studies involving patients which are associated with some scientifically debatable issues such as orienting towards surrogate endpoints. If claimed outcome and the actual endpoint do not match, there is a risk of skewed and exaggerated conclusions, attempts to forecast a favorable result, allocation of separate factors from primary multi-factorial studies. That is precisely why it is vital for the relevance of the whole study to take a balanced approach in selecting the right endpoints and to develop the research design according to this issue. Some studies (such as NETWORK, ALMAZ, ValHeFT) came to debatable results due to setting the surrogate endpoints (e.g. intima-media reflex, creatinine level, ST-segment descent) which are easier to measure and allegedly have more prognostic value for real clinical practice. On the contrary, the precise and detailed scientific analysis in bioequivalence studies hold strong evidence basis and are less exposed to bringing controversial results. As far as the correlation between the surrogate and real endpoints is not always definite, surrogate endpoints cannot be used as a basis for drug licensing and altering clinical practice pattern.

Biography

Vladyslava Chernykh has completed her Master's degree at Kharkiv National Medical University, Kharkiv, Ukraine. Currently, she is serving internship in Internal medicine at Kharkiv National Medical University. She is the author of two research papers in reputed journals and a contributing author to the patent. She has been working as healthcare personnel in more than 10 trials of Bioequivalence studies at Clinical and Diagnostics Center of the National University of Pharmacy.

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