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Toxicological evaluation of Zishen Yutai pill in beagle dogs: a 39 weeks oral gavage study

Miscarriage is a common obstetric disease, occurring in 15% to 40% women of reproductive age. Various traditional Chinese medicines treating miscarriage have been widely used throughout the pregnancy race, which were defined as one category of the complementary and alternative medicines by the National Center for Complementary and Alternative Medicine. Thereby, the long term toxicology of these medicines and their impacts on liver is more and more concerned by clinical physicians and infertility couples. Zishen Yutai pill (ZYP) is one of the most commonly used Chinese medicines for miscarriage. The objective of this 39 weeks study was to investigate the potential long-term toxicity and hepatotoxicity of ZYP administered to beagle dogs at dose levels of 1.5, 3.0 and 6.0 g/kg bw/day by oral gavage and to determine reversibility of any findings after the four weeks recovery period. Physiological saline was used as control respectively. Clinical observation, mortality, body weight, blood pressure and electrocardiogram, clinical pathology, organ weights, histopathology, hormones and traditional and potential hepatotoxicity biomarkers were detected and recorded. There were no mortality or toxic clinical symptoms and abnormalities in both sexes of beagle dogs except for the expected exaggerated pharmacological effects typically associated with female reproductive organs, which typically induced on endometrial thickening, dilated lactiferous ducts in mammary gland and vigorous-growth of oocytes in ovary. No obvious ZYP-related hepatotoxicity was observed after 13 and 39 weeks of ZYP treatment. Based on these results, the no-observed-adverse-effect-level (NOAEL) of ZYP in dogs is higher than 6.0 g/kg when administered orally for 39 consecutive weeks. Therefore, this study has suggested that no drug related toxicity was induced by ZYP administered up to 6.0 g/kg bw/day to beagle dogs for nine months. Since this dose is approximately 24 times as much as the clinical dose, it indicates a good safety margin of this product.

Biography

Yongwei Luo has completed his PhD at the Department of Pharmacy, Fudan University, China in 2018. He is now working as a Study Director in National Evaluation Centre for the Toxicology of Fertility Regulating Drug, Shanghai, China, which has acquired the GLP certificate of CDA (China Drug Administration). He has been showing great expertise in the area of preclinical toxicity evaluation of new drugs for nearly 10 years and has published a number of articles in reputed international journals.

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