

A clinical trial on biological half life of bioactive protein from *Lumbricus rubellus*, DLBS1033 in healthy volunteers

Anggi Gayatri, author

Deskripsi Lengkap: <https://lib.ui.ac.id/detail?id=20497874&lokasi=lokal>

Abstrak

ABSTRACT

Background: DLBS1033 is a bioactive protein fraction extracted from *Lumbricus rubellus*, with fibrinogenolytic, fibrinolytic and anti-aggregation activities reported in an in vitro study. Plasma half-life is an important parameter to calculate its dose. This study was conducted to evaluate the biological half-life of DLBS1033 by measuring serial plasmin-antiplasmin (PAP) complex. PAP complex is a stable and inactive compound as a result of fibrinolysis process. Methods: this was an open-label clinical trial in healthy adult subjects. Subjects were divided into two groups to receive single dose drugs (received 3 x 490 mg) or repeated administration until steady state conditions (3 x 490 mg/day for 3 days). Blood samples for PAP complex measurement were collected at time 0 (before drug administration for single dose group), then at 0.5, 1, 1.5, 2, 3, 6, 8, 10, 12, and 24 hours after drug administration. Safety parameters used in this study were creatinine, prothrombin time (PT), activated partial thromboplastin time (aPTT), SGOT, and SGPT. Results: the biological half-life of DLBS1033 was calculated based on the mean of PAP complex concentration on each time sampling. In single dose group, the highest mean of PAP complex concentration was reached before drug administration. Our result showed that the activity of DLBS1033 could not be determined after single dose administration. In steady state condition, the PAP complex concentration increase in 2 hours after last drug administration. The biological half-life of DLBS1033 was 8.6 hours. There were no significant safety findings on all laboratory parameters and no serious adverse events. Conclusion: it is concluded that the fibrinolytic effects of DLBS1033 can be measured in steady state condition. The biological half-life of DLBS1033 in steady state condition was 8.6 hours. There were no serious adverse events on two groups of subjects.