

레베셀(DDB-S)주의 안전성, 내약성 및 약동학적 특성평가

정재용, 임형석, 홍경섭, 배균섭, 이소영, 조주연, 유경상, 장인진, 신상구

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Evaluation of safety, tolerability, and pharmacokinetic characteristics of Levesel DDB-S(injection)

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Objective : To evaluate safety, tolerability, and pharmacokinetics of DDB(Dimethyl Dimethoxy Biphenylate)-S

Methods : Single dose trial was conducted in 24 healthy Korean subjects with single blind, randomized, placebo controlled parallel-group design (4 group: 7.5,15,30,60mg).

DDB-S was administrated by intravenous infusion during 60 minutes.

Results : Total 13 cases of adverse event are mild, temporary, and spontaneously recovered. There were no differences in PK parameters between groups. Linear regression analysis confirmed PK linearity within this dose range. The pharmacokinetic data were explained by one compartment model. Half of dose(49.86 ± 10.97 %) was excreted as unchanged form by kidney.

Conclusion : DDB-S was safe in Korean healthy subjects. It showed linear pharmacokinetic characteristics. Phase II clinical study for patients will be conducted.