

**Multiple-dose escalation, safety, and tolerability study of wood creosote, the principal active ingredient of seirogan, an herbal antidiarrheal medication, in healthy subjects**

Kuge T., Shibata T., Willett M. S.

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健常被験者に複数用量を多回投与した正露丸の主成分である木クレオソートの安全性、耐性試験

[Abstract]

Seirogan, an herbal medicine containing wood creosote (CAS 8021-39-4), a mixture of simple phenolic compounds, has been marketed for the past century in Asia for the treatment of acute diarrhea and associated symptoms, such as abdominal discomfort and cramping. The present study was designed to assess the safety and tolerability of an anticipated acute antidiarrheal dosing regimen. Sixty healthy males were randomized into five groups of 12 subjects each (9 wood creosote; 3 placebo) to receive 45-, 90-, 135-, 180-, and 225-mg tablets every 2 hours for five doses. Serial sitting and standing vital signs, ECG rhythm strips, and continuous telemetry monitoring were obtained predose and for 24 hours after the first dose. Clinical laboratory tests and 12-lead resting ECGs were obtained predose and 24 hours postdose. Of the subjects, 27% (12/45) receiving wood creosote and 27% (4/15) receiving placebo reported adverse events. The most common adverse events were altered taste and somnolence, reported more often with 180- and 225-mg doses. Wood creosote had no clinically significant effects on vital signs, ECG intervals or interpretations, or clinical laboratory tests. No clinically significant or serious dysrhythmias were reported on continuous telemetry monitoring. It was concluded that oral doses of wood creosote 45 to 225 mg every 2 hours for up to five doses were safe and well tolerated in 45 healthy subjects. Wood creosote doses ranging from 45 to 135 mg per dose, which are commonly administered antidiarrheal doses in Asia, were associated with minimal side effects.

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