

Treatment of Renal Stones with Frankincense: A Dream to be Translated into a Clinical Trial

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ABSTRACT

Frankincense (Luban) is a resin obtained from trees of genus *Boswellia*. The south of Oman hosts *Boswellia sacra* (BS) trees known to have many medicinal uses. Renal stones are common and people prefer non-surgical treatment approaches such as natural products. Recently, Al-Marhoon *et al.* have proved that Luban has a significant effect in the treatment and prevention of experimentally induced renal stones in rats-model. The aim of this phase I & II (Safety, Efficacy) randomized double-blind placebo-controlled clinical trial, is to explore the safety and efficacy of a novel boswellic acids (Luban-S) in the treatment of renal stones. The study will involve 34 participants divided into phase I (n=18) and phase II (n=16). Phase I to determine the safe dose (maximum tolerated dose) gradually testing 3 levels of daily doses (3000 mg, 5000 mg, 10000 mg) as calculated based on our pre-clinical animal study and pilot clinical trials, will be used in two and three divided doses to determine the proper scheduling of treatment (BID or TID). Once the safe dose and proper schedule is determined, phase II case-control study will proceed to examine the efficacy of the new drug (Luban-S) in patients with radiopaque and radiolucent renal stones (placebo n=8; Luban-S n=8). The inclusion criteria are: adult male and female patients with renal stones ≤ 10 mm in size. The exclusion criteria are: pregnant women, patients with known existing renal pathology or comorbidities such as DM, CKD, multiple renal cysts and renal tumors. The outcome measures of the study will include: a) Primary end point: effect of three months Luban-S treatment on the stone size (50% reduction or complete disappearance) or relieve of stone symptoms (50% reduction of symptoms); and b) Secondary end point: patients' intolerance of the treatment (toxicity) or development of side effects. If this study proves an effect of Luban-S on renal stones it will be an outbreak in the management of renal stones using an effective and safe eco-friendly natural product.

