NovaSil clay intervention in Ghanaians at high risk for aflatoxicosis. I. Study design and clinical outcomes.

A 3-month double-blind and placebo-controlled, phase IIa clinical trial was conducted in Ghana to investigate the safety, tolerance and aflatoxin-sorption efficacy of dietary NovaSil (NS). Volunteers (507 subjects) were clinically screened to evaluate their general health, pregnancy status and blood AFB(1)-albumin adduct levels. Of these subjects, 177 were randomly assigned to three groups: high-dose (HD), low-dose (LD) and placebo-control (PL) groups receiving 3.0, 1.5 and 0 g NS day(-1) in capsules. Trained study-monitors supervised NS capsule administration to participants and recorded side-effects daily. Physical examinations were performed monthly. Blood and urine samples were collected for laboratory analysis. Approximately 92% of the participants (162 of 177) completed the study and compliance rate was over 97%. Overall, 99.5% of person x time reported no side-effects throughout the study. Mild to moderate health events (approximately 0.5% of person x time) were recorded in some participants. Symptoms included nausea, diarrhea, heartburn and dizziness. These side-effects were statistically similar among all three groups. No significant differences were shown in hematology, liver and kidney function or electrolytes in the three groups. These findings demonstrate that NS clay is apparently safe and practical for the protection of humans against aflatoxins in populations at high risk for aflatoxicosis.