A phase 1 acute and sub-acute safety clinical trial and proof of concept efficacy of carbohydrate derived fulvic acid (CHD-FA)

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INTRODUCTION

CHD-FA is a new heavy metal free carbohydrate derived fulvic acid. Preclinical data indicated that CHD-FA is safe. It is also effective in inhibiting carrageenan induced inflammation in rats to an extent similar to indomethacin (unpublished results). The next stage was to test the safety and efficacy of CHD-FA in humans.

METHODS

In this double blind study 30 male volunteers with a predetermined atopy were randomly assigned to groups A and B, each consisting of 15 participants. In phase 1 the groups were alternatively administered increasing amounts of 4.8% CHD-FA ranging from 5ml to 40ml, provided no adverse events occurred.

In phase 2, group A received 20ml CHD-FA twice per day for a period of 3 days and monitored for a week. As no adverse events occurred, group B received 40ml CHD-FA twice per day for a period of 3 days. In phase 3 both groups received either 40ml CHD-FA or placebo twice a day for a period of one week after which they underwent a one week washout period before crossing over to opposite treatments.

Parameters used to establish safety were ECG's, physicals, questionnaires and haematology and biochemistry analysis which were determined at the beginning, during regular calculated intervals, and at the end of each phase. Skin prick tests using the appropriate allergens, were performed during screening and again at the beginning and end of phase 3 to determine efficacy.

RESULTS

Safety parameters remained constant throughout the trial with diarrhoea and headache being the only major side effects after ingesting the 40ml dosages, with headaches subsiding after a short time period and diarrhoea alleviated with the ingestion of food (Figures 1, 2, 3 and 4). A significant decrease in the skin prick test results was observed (Table 1).

Table 1:
Measurements of wheal (diameter in mm) before and after the study of the treated vs placebo groups with respect to their skin prick tests.

	Diameter of wheal (mm)			
	Before		After	
	Mean	SD	Mean	SD
Fulvic Acid	6.63	3.64	4.97*	3.26
Placebo	7.03	4.15	6.73	3.98

* Indicating statistical significance ($p < 0.05$)

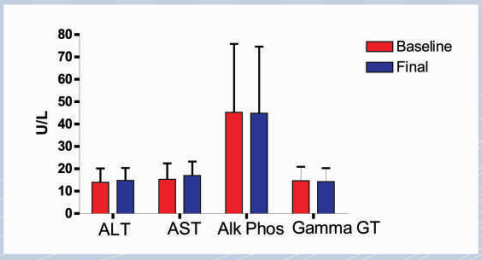

Figure 1: Liver function results.

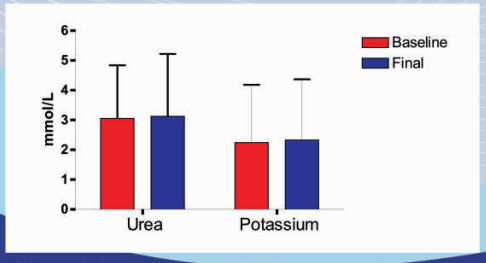

Figure 3: Kidney function results.

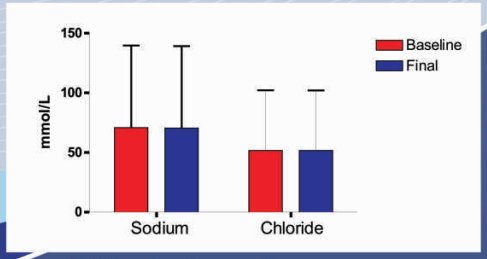

Figure 2: Kidney function results.

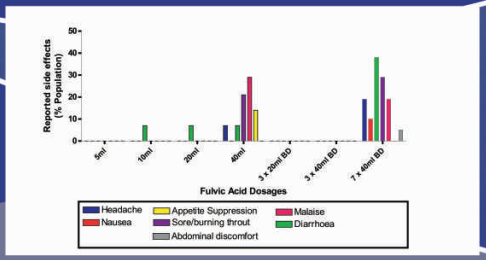

Figure 4: Summary of side effects of

CONCLUSION:

No severe adverse events occurred, proving fulvic acid to be safe at a 40ml dosage twice daily for a week, and at this dosage proving, with a significant decrease in wheal formation in the skin prick test, that it is systemically available and acts as an anti-inflammatory agent.