Progress Report: Sri Lanka Clinical Trials Registry

SLCTR registration number: SLCTR/2013/001

Scientific title of trial: Evaluation of pharmacodynamic properties and the safety of *Cinnamomum zeylanicum* (Ceylon cinnamon) in healthy adults

Date of commencement (enrolment of first participant): 26/1/2014

Progression: 6 months ☐ 1 year ☐ 2 years ☐ 3 years ☐

At completion ■

1. Baseline data

Any changes to the trial design/ methodology/ protocol after commencement: Yes

Any changes to trial outcomes after commencement: No

2. Current status

Recruitment status: Clinical trial on Healthy volunteers - completed

Number assessed for eligibility: 30

Number recruited and randomized: N/A

Number allocated to each intervention/arm: 30

Losses/exclusions after randomization: 0

3. Trial output

Summary of Interim/Final data (if available): Summary of results attached

Presentations of results at scientific meetings: N/A
(Please attach a scanned copy or link to abstract)

Publications: N/A (Under review)
(Please attach a scanned copy or link to paper)

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Name and signature of Responsible Registrant

Date: 23rd March 2017

Prof. P. Galappatthy
Principal Investigator

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Summary of Results

The clinical trial was conducted for a period of 3 months. Data collection was carried out by trained medical research assistants, using a standardized case record form, at baseline (Visit '0) and during each monthly follow up visit (Visit '1', '2' and '3'). *Cinnamomum zeylanicum* capsules were supplemented over a period of three months in escalating doses. Both systolic and diastolic blood pressure reduced significant during the 1st month and this reduction was sustained throughout the 3 months follow up period (Table 1). When the lipid parameters were considered, the HDL-c, VLDL-c and TG remained unchanged during follow up. However, a significant reduction in the TC ($p<0.05$) and LDL-c ($p<0.001$) was noted at the end of the 3 months follow up period. There were no serious adverse effects noted and none of the subjects were hospitalized during the 3 months follow up period. Biochemical assessments evaluating potential target organ toxicity (liver and renal function tests) remained normal throughout the study period. None of the patients experienced any form of hypersensitivity during the study (immediate and/or delayed).

TABLES

Table 1: Clinical and biochemical assessment during follow up

	Mean±SD							
	Visit '0' (Baseline) Screening	Visit '1' (1 month)	Visit '2' (2 months)	Visit '3' (3 months)	P1*	P2*	P3*	P4*
Pulse rate (min^{-1})	73.4±8.4	71.9±9.2	71.5±8.4	75.8±8.6	NS	NS	<0.05	NS
Systolic Blood Pressure (mmHg)	124.0±10.8	118.0±12.8	117.7±13.2	117.3±11.1	<0.001	NS	NS	<0.01
Diastolic Blood Pressure (mmHg)	76.8±8.4	72.7±11.5	71.9±9.1	72.0±8.2	<0.05	NS	NS	<0.01
Weight (kg)	66.5±11.5	66.5±11.2	66.7±11.6	66.4±11.5	NS	NS	NS	NS
Body Mass Index (kgm^{-2})	24.8±3.6	24.8±3.5	24.8±3.7	24.7±3.8	NS	NS	NS	NS
Waist circumference (cm)	86.6±10.6	85.5±9.1	85.6±9.4	85.6±8.8	NS	NS	NS	NS
Hip circumference (cm)	97.8±9.0	96.4±8.4	96.2±8.9	96.0±9.3	<0.05	NS	NS	<0.05
Waist to Hip ratio	0.9±0.1	0.9±0.1	0.9±0.1	0.9±0.1	NS	NS	NS	NS
Haemoglobin (g/dl)	14.3±1.6	NM	NM	14.5±1.8	-	-	-	NS
White blood cell count ($*10^9$ per mm^3)	6.1±0.5	NM	NM	6.3±0.9	-	-	-	NS

Platelet count (*10^9 per mm^3)	202.8±10.7	NM	NM	208.4±18.4	-	-	-	NS
Fasting blood glucose (mg/dl)	91.2±6.9	94.5±11.7	93.0±7.6	92.7±9.6	NS	NS	NS	NS
Serum creatinine (mg/dl)	0.9±0.2	0.9±0.2	0.8±0.2	0.9±0.2	NS	NS	NS	NS
AST (U/l)	27.9±7.3	29.7±7.7	29.2±7.5	27.6±6.3	NS	NS	NS	NS
ALT (U/l)	21.0±10.9	23.4±10.9	21.7±10.5	19.2±11.2	NS	NS	NS	NS
Serum bilirubin (mg/dl)	0.8±0.4	0.6±0.3	0.5±0.4	0.7±0.4	NS	NS	NS	NS
PT/INR	1.1±0.1	1.1±0.1	1.1±0.1	1.1±0.1	NS	NS	NS	NS
Total cholesterol (mg/dl)	226.4±38.7	NM	NM	210.24±50.9	-	-	-	<0.05
LDL cholesterol (mg/dl)	152.8±37.1	NM	NM	129.8±47.4	-	-	-	<0.001
HDL cholesterol (mg/dl)	52.7±14.2	NM	NM	61.8±21.4	-	-	-	NS
VLDL cholesterol (mg/dl)	24.6±15.2	NM	NM	27.6±22.7	-	-	-	NS
Triglycerides (mg/dl)	112.1±49.9	NM	NM	115.0±47.9	-	-	-	NS

ALT – Alanine aminotransferase; AST – Aspartate aminotransferase; CZ – *Cinnamomum zeylanicum;* HDL – High Density Lipoprotein; LDL – Low Density Lipoprotein; INR – International Normalized Ratio; NM – Not Measured; NS – Not Significant; PT – Prothrombin Time; VLDL – Very Low Density Lipoprotein; *P1 – Baseline vs Visit 1; *P2 – Visit 1 vs Visit 2; *P3 – Visit 2 vs Visit 3; *P4 – Visit 0 vs Visit 3