EFFECTS OF OMEGA 3 FATTY ACIDS SUPPLEMENTATIONS ON NONALCOHOLIC FATTY LIVER DISEASE PATIENTS, A PILOT STUDY

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19th June 2017

Dr. Md. Ayub Al Mamun
Associate Professor
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Dear Dr. Mamun,

Sri Lanka Clinical Trials Registry – Trial Registration Confirmation Letter

Scientific Title: Efficacy of Silymarin (Milk Thistle fruit extract) compared to placebo in improving liver fibrosis in patients with non-alcoholic fatty liver disease, a Pilot Study

Application no: APPL/ 2017/022

Thank you for submitting your clinical trial to the Sri Lanka Clinical Trials Registry. I am pleased to inform you that your trial has been registered. The registration details are as follows:

Registration No: SLCTR/ 2017/016

Date of Registration: 19th June 2017

The SLCTR is a Primary Registry linked to the WHO International Clinical Trials Registry Platform (WHO - ICTRP). The SLCTR registered trials can be accessed via the WHO - ICTRP website.

Please note the following, which are requirements of the WHO.

1. Maintenance of trial records: Please note that you are requested to
   a. Notify the SLCTR of the actual date of commencement of the trial
   b. Send updates of trial progress at 6 months following registration, and yearly thereafter until the trial is completed
   c. Notify the SLCTR of any changes to protocol
   d. Send details of publications (if any) which will be linked / uploaded in the SLCTR website
2. Deletion of the trial from the registry: once registered, no clinical trial may be deleted from the SLCTR.

We wish you well in your research efforts.

Yours sincerely

Prof. Colvin Goonaratna
Chairperson
Sri Lanka Clinical Trials Registry Committee

Introduction

- Nonalcoholic fatty liver disease **(NAFLD)** is the 3rd most common liver disease in world.

- In Bangladesh, the prevalence of NAFLD ranges from 4% to 18.4% in general population.

- Supplementations of Omega 3 Fatty Acids, by enhancing beta oxidation reduce endogenous lipid production.

- It also reduces inflammatory markers and improves insulin sensitivities.

Study Objective

In this study we assessed the improvement of hepatic fibrosis after supplementations of Omega 3 Fatty Acids by **Fibroscan Score of Liver in NAFLD** patients.

Patient Selection

Inclusion criteria

1. Ultrasonography of hepatobilliary system suggests Fatty Liver

Exclusion criteria

1. Co-infection with HBV or HCV

Methods

- In group 1, N=20 and in group 2, N=80 (total=100)

- All patients got appropriate diet and lifestyle modification and appropriate treatment for co-morbid diseases.

- Along with this Group 1 was given Placebo and Group 2 was given Cap Omega 3 Fatty Acids 1gm twice daily for 6 months.

Primary end point: After 6 month of treatment

Secondary end point: Patient safety

Effects of Omega 3 Fatty Acids supplementations on Nonalcoholic Fatty Liver Disease patients, A Pilot Study

Month	0	6
Group 1 (N = 20)	**Placebo**	
Group 2 (N = 80)	**Cap Omega 3 Fatty Acids 1gm**	

Drug Dosing

Group 1 : Placebo daily for 6 month

Group 2 : Cap Omega 3 Fatty Acids 1 gm, 1 cap twice daily for 6 month

Results

Table 1: Baseline demographics and disease characteristics

Characteristic	Group 1 (N=20)	Group 2 (N=80)
Male	6 (30%)	33(41.25%)
Age, years(mean, SD)	39.8(11.7)	40.98(10.82)
SGPT(range)IU/ml	13-82	10-186
SGOT(range)IU/ml	16-91	10-128
Obesity	8(40%)	40(50%)
DM	6(30%)	30(37.5%)
HTN	6(30%)	40(50%)
Hypothyroidism	2(10%)	16(20%)
IHD	0(0%)	2(2.5%)
Fibroscan, Kappa, (range)	3.2-9	3.3-21.1

Table 2: Effects before and after treatment in Control group

	Control (N=20)		
	Before treatment	After treatment	P value
SGPT (mean, SD) IU/ml	38.55(20.148)	37.35(22.693	.848
SGOT (mean, SD) IU/ml	34.25(20.097)	28.70(13.031)	.271
Fibroscan of Liver (mean, SD) Kpa	6.055(1.781)	4.825(1.0548)	**.011**

Table 3: Effects before and after treatment in Case group

	Case (N=80)		
	Before treatment	After treatment	P value
SGPT (mean, SD) IU/ml	39.19(26.825)	39.11(27.721)	.976
SGOT (mean, SD) IU/ml	34.31(21.570)	30.73(17.175)	.065
Fibroscan of Liver (mean, SD) Kpa	6.148(2.3734)	6.209(2.9369)	.783

Table 4: Common clinical adverse events during and after treatment

Characteristic	Group 1 (N=20)	Group 2 (N=80)	P value
Nausea and vomiting	0 (0%)	5(6.25%)	.388
Epigastric discomfort	0(0%)	4(5%)	.458
Abdominal pain	0 (0%)	2(2.5%)	.764
Diarrhea	0 (0%)	6(7.5%)	.410
Drug discontinuation	0 (0%)	0 (0%)	0

Discussion

Nonalcoholic fatty liver disease **(NAFLD)** patients treated with appropriate diet and lifestyle modification and appropriate treatment for co-morbid diseases showed significant improvement **Fibroscan Score of Liver (p=.011).**

Supplementations of Omega 3 fatty acids had no added benefit on the basis of **Fibroscan Score of Liver** (p=.783) improvement.

Conclusion

Newer drugs for the treatment of **NAFLD** is very frustrating.

On the basis of improvement **Fibroscan Score of Liver,** supplementations of Omega 3 fatty acids shows frustrating results.

Thank you