Safety and efficacy of BoozLiv™ in patients with alcoholic liver disease: An open-label, randomized trial

Institutional Human Ethics Committee Permission No. 8283/IEC/2022

Clinical Trial Registry: CTRI/2022/08/044978

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1. Introduction

Alcoholic liver disease (ALD) is a major cause of mortality and morbidity worldwide. There is a spectrum of alcoholic liver disease namely steatosis, hepatitis, cirrhosis and hepatocellular carcinoma. Long-term excess alcohol exposure leads to alcoholic liver disease-a global health problem without effective therapeutic approach. ALD is increasingly considered as a complex and multifaceted pathological process, involving oxidative stress, inflammation and excessive fatty acid synthesis. The use of alternative medicine such as herbal medicines, phytonutrients, ayurvedic products and nutraceuticals used widely by the majority of the patients for various health challenges around the world. Based on the existing data, use of herbal medicines as a supplemental therapy in alcoholic liver disease has a greater therapeutic outcome. BoozLiv™ is a unique formula is made from natural herbs and nutrients that are known to support liver health and promote liver detoxification. This helps to eliminate toxins from the liver and improve liver function. As BoozLiv™ siddha formulation have anti-oxidants, hepato protective and appetite stimulating properties but there is no further clinical evidence in safety and efficacy of the BoozLiv™ formulation. Hence, we have designed a randomized open-label trial to estimate the efficacy and safety of the BoozLiv™ in alcoholic liver disease patients

2. Objectives

Primary Objectives

- To determine the effect of BoozLiv™ add-on therapy in the liver function parameters at 30th, 60th and 90th day of follow-ups.

Secondary Objectives

- To observe and assess the adverse events during the study period.
- Using MELD Score to determine the severity of the disease

3. Methodology

3.1. Study Design

Randomized, open-label trial

3.2. Study Site

Department of Medical Gastroenterology, SRM Medical College Hospital and Research Centre

3.3. Ethical Considerations

This study was conducted according to the standards of the International Committee on Harmonization on Good Clinical Practice and the revised version of the Declaration of Helsinki. The institutional human ethics committee of SRM Medical College Hospital and Research Centre approved this study protocol **(8283/IEC/2022)** followed by study was registered in Clinical Trial Registry India (CTRI). **(CTRI/2022/08/044978)**

3.4. Study Duration

12 months

3.5. Sample Size

Pilot Study (30 Patients in each group)

3.6. Investigational Product

Each 10ml of Syrup contains,

Wedelia calandulacea	350mg
Phyllanthu niruri	350mg
Piper nigrum	100mg
Pimpenella anisum	100mg
Aegle marmalos	120mg
Andrographis paniculata	140mg & Excipients q.s

3.7. Inclusion Criteria

- Adults aged over 18 years with the evidence of alcoholic liver disease (ALD) based on a thorough history, physical examination, and laboratory tests
- Chronic alcohol intake, Identified with AUDIT (Alcohol Use Disorder Inventory Test) Questionnaire
- Active alcohol use until 4 weeks prior to presentation
- ALT and AST elevated >1.5 times the upper limit of normal
- Over 1.5 ratio of AST to ALT
- Patients willing to participate in the study

3.8. Exclusion Criteria

- Severe alcoholic hepatitis with cirrhosis or life expectancy less than 3 months
- Severe renal impairment (Glomerular filtration rate below 60 ml/min per 1.73m^2)
- Hepatic disorders due to cardiac causes, inherited metabolic causes, hemochromatosis and Wilson's disease
- Participants with active viral hepatitis
- undergoing active treatment for alcohol withdrawal syndrome (AWS) at the study entry
- Participants on hepatotoxic medications like antitubercular medication, antiviral medication, paracetamol etc.
- Pregnant, attempting to conceive, or lactating women Participating in another clinical trial with an active intervention or drug or device with last dose taken within 60 days

3.9. Treatment Groups

Group A - Control Group (Thiamine + Vitamin K +Ursodeozycholic acid)

Group B - Control + BoozLiv™ 10ml twice daily

4. Study Procedure

A randomized, open-label, pilot trial will be conducted for a duration of 12 weeks wherein treatment will be assigned using a randomization code (Random Allocation Software V 2.0) in the ratio of 1:1. Liver function tests, MELD scoring system and quality of life will be estimated at the baseline (before treatment), 30th, 60th and 90th day after the treatment to determine the efficacy of BoozLiv^{TM} in the alcoholic liver disease patients.

4.1. Measurement of anthropometric indices

Demographic information was achieved by a questionnaire. Height and body weight were measured without shoes and with the study subjects wearing light clothes. Height was measured to the nearest 0.1 cm, and weight was measured to the nearest 0.01 kg. Measurements were carried out using portable calibrated electronic weighing scale and inflexible measuring bars. BMI was calculated as weight/height^2 (kg/m^2).

4.2. Estimation of Liver function tests

Blood samples of 4 mL were obtained in the morning (8-10 am) by venous puncture after overnight fasting (at least 12 hours fasting). The serum was separated by centrifugation (5430R, Eppendorf). Total bilirubin, direct bilirubin, SGOT, SGPT, ALP, Ablumin, Globulin, Total Protein and GGTP was estimated through fully automated clinical chemistry analyzer (EM 360, Transasia) using Erba diagnostics kits (ERBA Diagnostics Mannheim GmbH).

4.3. Model for End Stage Live Disease (MELD) Score

The Model for End-stage Liver Disease (MELD) score was developed as a simple, and more objective hepatic score compared to Child-Pugh. It accurately predicts short-term mortality on the liver transplant waiting list, and its three variables: serum bilirubin, creatininemia, and international normalized ratio,

highlight the prognostic significance of the interactions between liver and renal functional variables in liver failure patients.

The MELD score formula is: 3.8[$\log_e$ serum bilirubin (mg/dL)] + 11.2 [$\log_e$ INR] + 9.6 [$\log_e$ serum creatinine (mg/dL)] + 6.4.

Table. 1. Schedule of study events

Schedule of Events					
Activities	**Screening**	**Enrollment Day o**	**Day 30**	**Day 60**	**Day 90**
Informed Consent	X				
Demographics	X				
Medical/Medication History	X				
Physical Examination	X		X	X	X
Vitals	X		X	X	X
Liver function tests	X		X	X	X
Inclusion/exclusion criteria check	X				
Randomization/enrollment		X			
Recording of AEs and SAEs		X	X	X	X
Concomitant medication		X	X	X	X
MELD Scoring System		X			X

4.4. Statistical analysis

Results were expressed in percentage and mean±standard deviation. Comparisons of baseline data among the two groups were performed through statistical package for social science (SPSS), software using t-test and calculated *P-values*.

5. Results

A total of 201 patients were assessed for eligibility, 133 patients were excluded because of not meeting the criteria (72) and unwillingness to participate (61) in the study. Finally, 68 patients included and were randomized into two groups. Group A received Standard therapy and Group B received standard therapy with BoozLiv™ (Figure.1). The baseline characteristics are mentioned in (Table.2).

Table 2. Patient baseline demographics

PARAMETERS	**GROUP A (Control)**	**GROUP B (Control + BoozLiv™)**	**P VALUE**
Age (Years)	44.43±10.89	46.39±8.56	0.68
Height (cm)	164.36±6.18	162.74±8.13	0.85
Weight (Kg)	82.96±6.65	77.6±5.45	0.56
BMI (kg/m^2)	27.62±2.83	26.7±2.25	0.16
PR (beats/min)	78.83±6.51	79.06±6.39	0.81
Hip Circumference (cm)	36.81 ± 1.51	35.25 ± 1.60	0.22
Waist Circumference (cm)	37.45 ± 1.55	38.23 ± 0.86	0.56
Systolic BP (mmHg)	140.16±8.28	136.46±7.02	0.48
Diastolic BP (mmHg)	85.73±4.94	87.4±8.52	0.24
Total Bilirubin	02.53±0.52	2.61±0.60	0.31
Direct Bilirubin	1.20±0.21	1.33±0.51	0.46

P>0.05 considered as non-significant

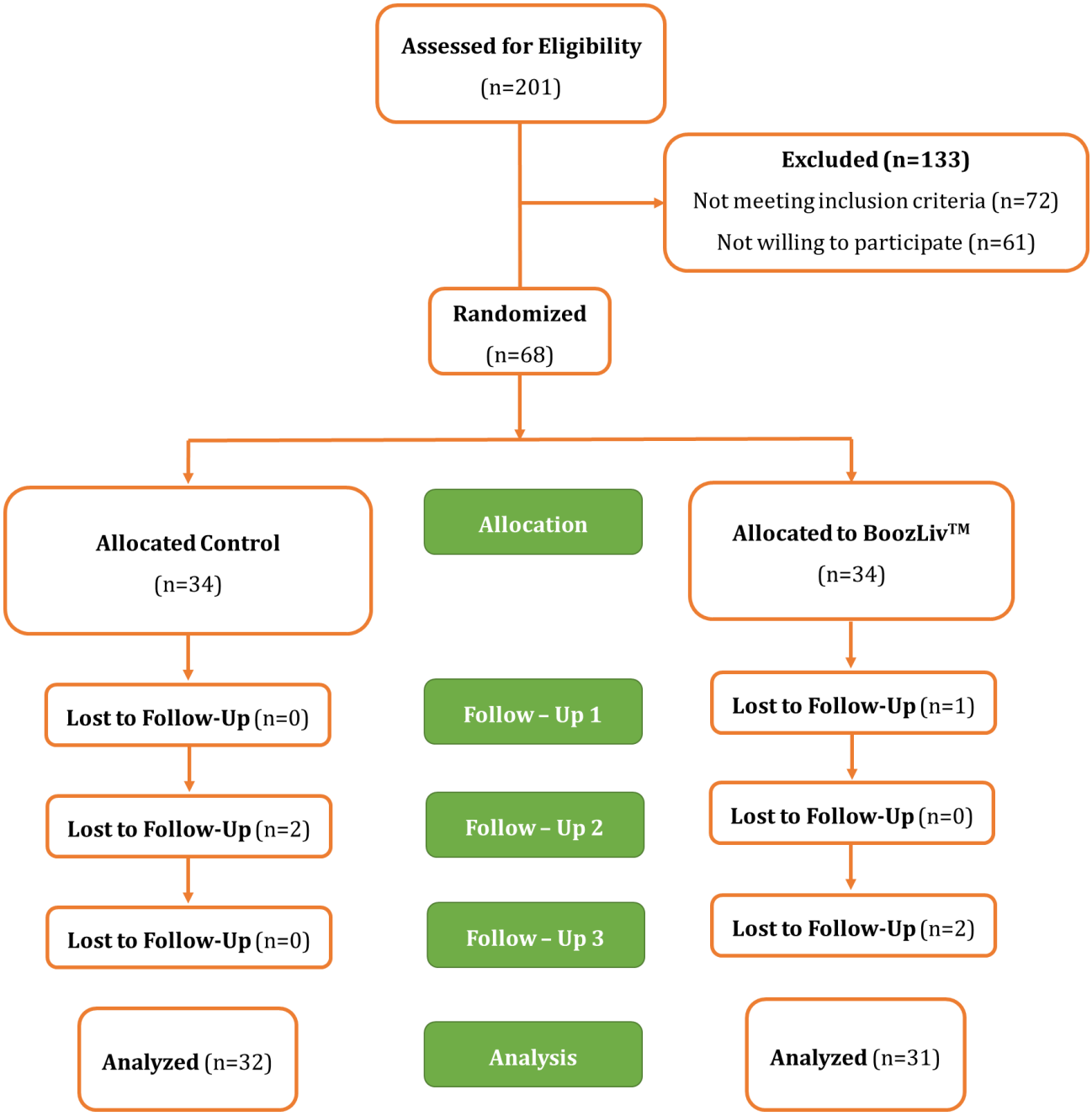


Figure 1. CONSORT flow chart

5.1. Patients Demographics

After getting informed consent, patients demographics was recorded for the both the groups. In the baseline comparison, there was no significant difference *($p>0.05$)* between age, BMI, pulse rate, hip circumference, waist circumference, blood pressure, total and direct bilirubin.

5.2. Effect of Control and BoozLiv™ add-on treatment on Total Bilirubin and Direct Bilirubin

Total and direct bilirubin levels were significantly decreased from the baseline to 3rd follow-up in patient receiving BoozLiv™ add-on therapy when compared to standard therapy. (Figure 2)

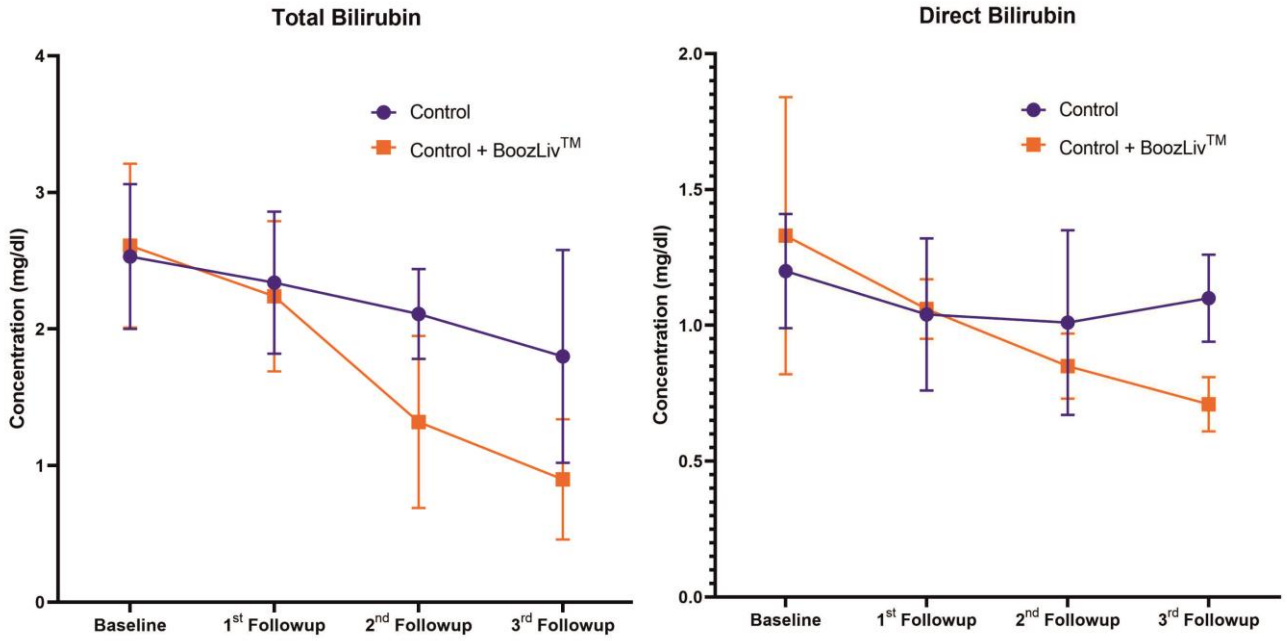


Figure 2. Comparative effect of Control and BoozLiv™ add-on treatment on Total Bilirubin and Direct Bilirubin *(Level of significance P<0.05*, P<0.01**, P<0.001*** and P>0.05 considered as non-significant)*

Key findings:

- BoozLiv™ add-on therapy significantly reduces the elevated levels of total bilirubin, direct bilirubin, SGOT, SGPT, ALP, GGPT and albumin in alcohol associated liver disease patients
- MELD total score indicated that clinically relevant improvement in the liver function observed in BoozLiv™ add-on therapy treatment
- Overall, BoozLiv™ showed synergistic potential benefits in the management of liver dysfunction associated with alcoholic liver damage.
- BoozLiv™ was found to be safe and was quite tolerable

5.3. Comparison of Control and BoozLiv™ add-on treatment effect on SGOT and SGPT

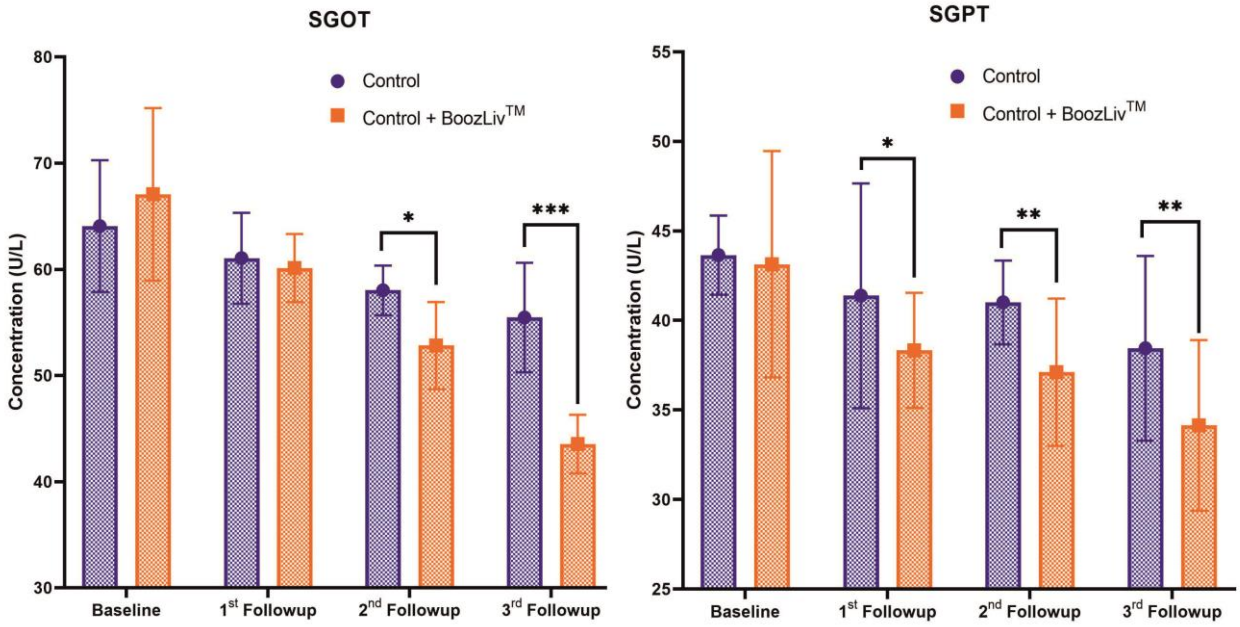


Figure 3. Effect of Control and BoozLiv™ add-on therapy on SGOT and SGPT *(Level of significance P<0.05*, P<0.01**, P<0.001*** and P>0.05 considered as non-significant)*

The results indicated that the BoozLiv™ add-on therapy significantly reduced the elevated levels of SGPT and SGOT in patients with alcoholic liver disease when compared to standard therapy (Figure 3). BoozLiv™ add-on therapy has reduced the SGPT levels from 43.14±6.32 U/L to 34.02±3.76 U/L and SGOT levels from 67.06±8.12 U/L to 43.55±2.76 U/L. (Figure 3)

5.4. Effect of Control and BoozLiv™ add-on treatment on ALP and GGTP

ALP significantly reduced in 2nd follow-up and 3rd follow-ups in BoozLiv™ group when compared to standard therapy group. GGTP shown significant difference in 3rd follow-up of BoozLiv™ add-on therapy when compared to standard therapy. (Figure 4)

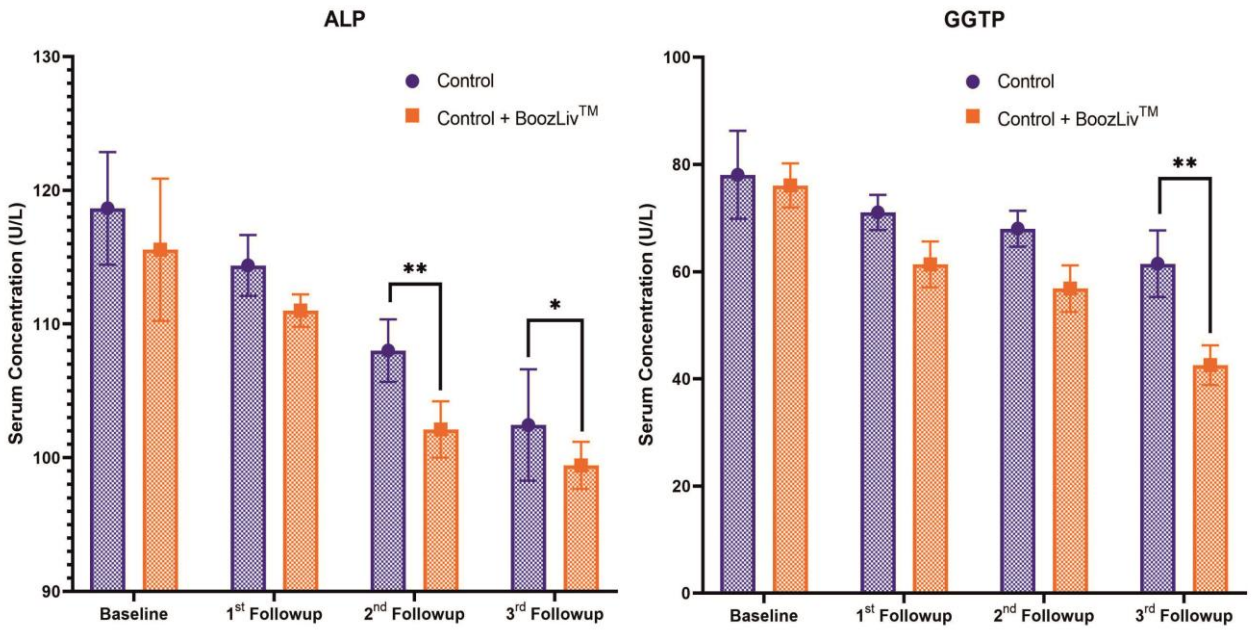


Figure 4. Comparative effect of Control and BoozLiv™ add-on treatment on ALP and GGTP *(Level of significance P<0.05*, P<0.01**, P<0.001*** and P>0.05 considered as non-significant)*

5.5. Influence of Control and BoozLiv™ add-on treatment on Albumin, Globulin and Total Protein

After the 3rd follow-up, serum albumin concentration was significantly decreased in BoozLiv™ add-on treatment when compared to standard treatment. No difference was found in the serum globulin and total protein after 3rd follow-up between the control and BoozLiv™ add-on therapy group. (Figure 5)

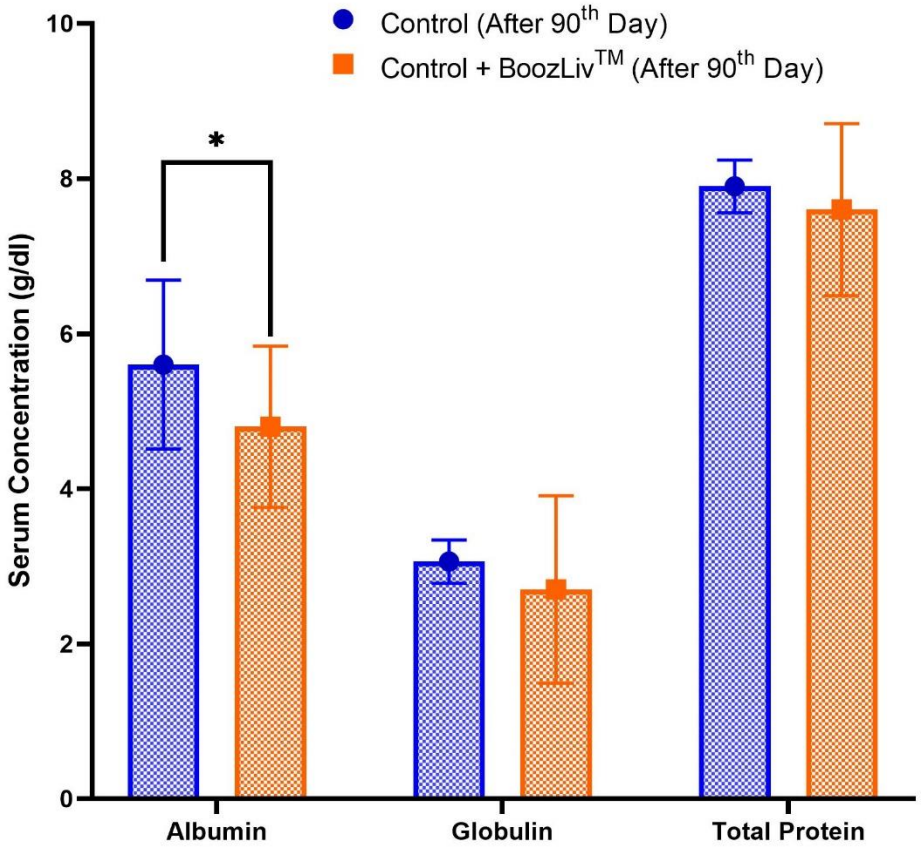


Figure 5. Effect of Control and BoozLiv™ add-on treatment on Albumin, Globulin and Total Protein *(Level of significance P<0.05*, P<0.01**, P<0.001*** and P>0.05 considered as non-significant)*

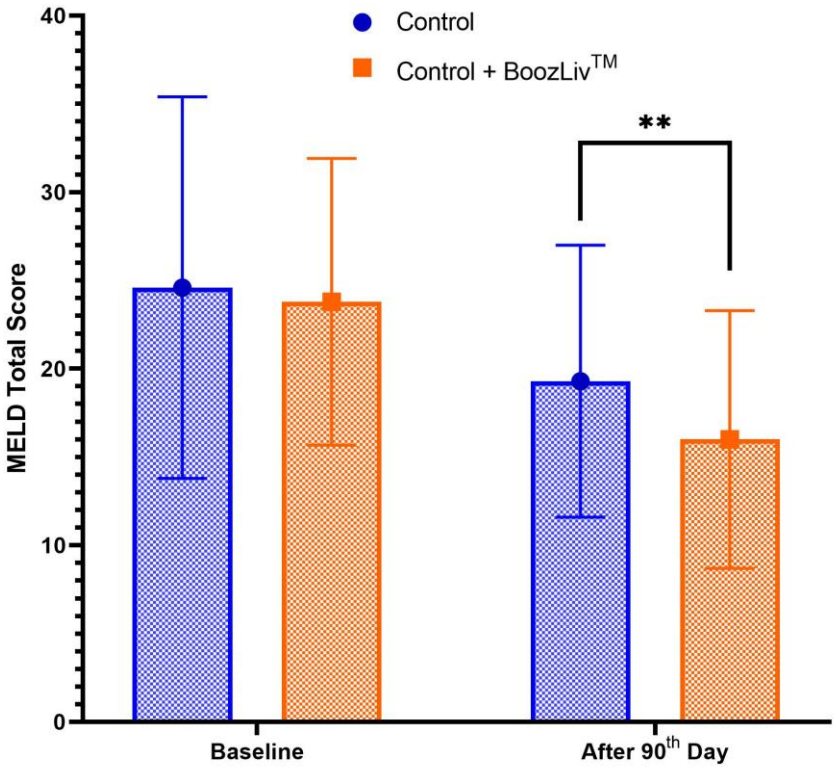
5.6. Impact of BoozLiv™ treatment on MELD Score

Based on the results, a significant decrease *(p<0.01)* in the MELD total Score was observed in the BoozLiv™ add-on therapy when compared to standard treatment. This shows clinically relevant improvement in the liver function.

5.7. Safety analysis

BoozLiv™ was found to be safe and was quite tolerable in most of the patients with alcoholic liver disease. The most common adverse events recorded in our study were nausea, vomiting and gastritis but no patient had withdrawn their consent from the study due to these events. All the recorded ADRs were

reported to the Pharmacovigilance centre, SRM Medical College Hospital and Research Centre periodically.



6. Conclusion

BoozLiv™ add-on therapy at the dose of 10ml twice daily for 12 weeks showed remarkable improvement in the liver parameters such as total bilirubin, direct bilirubin, SGOT, SGPT, ALP, GGPT and albumin. Significant reduction in the MELD score was observed in the BoozLiv™ add-on therapy when compared to standard treatment. It was relatively safe with a good tolerability profile and no SAEs attributed to BoozLiv™. However, long-term studies in a larger population should be conducted to confirm our findings in patients with mild–moderate alcoholic liver disease.

7. References

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8. Acknowledgement

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Annexure I

SRM MEDICAL COLLEGE HOSPITAL & RESEARCH CENTRE

SRM
INSTITUTE OF SCIENCE & TECHNOLOGY

ETHICS CLEARANCE NUMBER: 8283 */IEC/2022*

Proceeding of Institutional Ethics Committee

The Institutional Ethics Committee Discussed "Safety and efficacy of BooZLiv™ in patients with alcoholic liver disease : An open-label, randomized controlled trial"- by Mr.Balavigneshwaran, Pharm.D Student - Guided by Dr.T.M.Vijayakumar, Associate Professor & Head, Dept. of Pharmacy Practice, SRM College of Pharmacy, SRMIST on 25.03.2022 at 10.00 AM. The Ethics Committee approved the project and the progress will be reviewed periodically.

Jamuna Rani
Member Secretary
Institutional Ethics Committee

SRM MEDICAL COLLEGE HOSPITAL & RESEARCH CENTRE
EC NO: 8283
Date: 25.3.2022
INSTITUTIONAL ETHICS COMMITTEE

Copy to :
Mr.Balavigneshwaran

SRM Nagar, Potheri, Kattankulathur-603203, Chengalpattu District, Tamilnadu, India.
Phone - Hospital off.: 044 - 47432333, 47432307, 47432367, College: 47432502
Fax: 27455106, Web: www.srmist.edu.in

Annexure II

Informed consent Form

Study Title:

Study number:

Subject initials: **Age:**

Subject Name:

I confirm that I have read and understood the information sheet dated _____ for the above study and have had the opportunity to ask questions. I understand that my participation in the study is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected. I understand that the investigator and the ethics committee will not need my permission to look at my health records both in respect of the current study and any further research that may be conducted in relation to it, even if I withdraw from the trial. I agree to this access. However I understand that my identity will not be revealed in any information released to third parties or published. I agree not to restrict the use of any data or results that arise from this study provided that such a use is only for scientific purpose.

I agree to take part in the above study

Signature (or thumb impression) of the subject/legally accepted representative:

_____ Date: _____

Signatory name: _____

Signature of the investigator _____ Date

Study investigator name: _____

Signature of the witness: _____

Date: _____

Name of the witness: _____

Annexure III

நோயாளியின் ஒப்புதல் படிவம்

ஆராய்ச்சியின் எண்:

ஆராய்ச்சியின் பெயர் :

ஆய்வுக்கு உட்படுவரின் பெயர்..... வயது:

எனக்கு இந்தச் சோதனையின் அனைத்து விவரங்களும் என் மொழியில் விளக்கப்பட்டது. இந்த சோதனையை நன்கு புரிந்துகொண்டேன். ஆகவே இந்தச் சோதனைக்கு உட்பட என்னுடைய விருப்பத்தை உறுதிப்படுத்துகிறேன். இந்தச்சோதனையில் என்னுடைய சொந்த விருப்பத்தில் பங்கேற்கிறேன். இதிலிருந்து எந்தக் காரணமும் கூறாமல் எப்போது வேண்டுமானாலும் விலகிக் கொள்ளலாம் என அறிவேன். அறிவியல் நோக்கங்களுக்காக மட்டுமே இந்த ஆய்வின் தரவுகள் அல்லது முடிவுகள் பயன்படுவதை கட்டுப்படுத்தமாட்டேன் என உறுதி கூறுகிறேன். இதன் வாயிலாக இந்த சோதனையில் ஓர் அங்கமாக இருக்க என்னுடைய முழு ஒப்புதலையும் அளிக்கிறேன்.

நோயாளியின் கையொப்பம் /
கட்டை விரல் ரேகைப் பதிவு

நடுநிலைச் சாட்சியின் கையொப்பம்

நாள்:

கையொப்பதாரரின் பெயர் :

ஆய்வாளரின் கையொப்பம் :

ஆய்வாளரின் பெயர் :

நடுநிலைச் சாட்சியின் பெயர் :

- நோயாளி கல்வியறிவு பெறாதவராக இருக்கும் பட்சத்தில் நடுநிலைச் சாட்சியின் கையொப்பம் தேவைப்படுகிறது. நடுநிலை சாட்சி நோயாளியின் தகவல் படிவம் மற்றும் நோயாளியின் ஒப்புதல் படிவத்தை நோயாளிக்குப் புரியும் மொழியில் படித்துக் காட்ட வேண்டும்.

Annexure IV

Version-1.2

SUSPECTED ADVERSE DRUG REACTION REPORTING FORM

For VOLUNTARY reporting of Adverse Drug Reactions by Healthcare Professionals

INDIAN PHARMACOPOEIA COMMISSION
(National Coordination Centre-Pharmacovigilance Programme of India)
Ministry of Health & Family Welfare, Government of India
Sector-23, Raj Nagar, Ghaziabad-201002

FOR AMC/NCC USE ONLY

AMC Report No. :

Report Type ☐ Initial ☐ Follow up

Worldwide Unique No. :

A. PATIENT INFORMATION

1. Patient Initials _____

2. Age at time of Event or Date of Birth _____

3. M ☐ F ☐ Other ☐

4. Weight_____Kgs

12. Relevant tests/ laboratory data with dates

B. SUSPECTED ADVERSE REACTION

5. Date of reaction started (dd/mm/yyyy)

6. Date of recovery (dd/mm/yyyy)

7. Describe reaction or problem

13. Relevant medical/ medication history (e.g. allergies, race, pregnancy, smoking, alcohol use, hepatic/renal dysfunction etc.)

14. Seriousness of the reaction: No ☐ if Yes ☐ (please tick anyone)

☐ Death (dd/mm/yyyy) ☐ Congenital-anomaly
☐ Life threatening ☐ Required intervention to Prevent permanent impairment/damage
☐ Hospitalization/Prolonged
☐ Disability ☐ Other (specify)

15. Outcomes

☐ Recovered ☐ Recovering ☐ Not recovered
☐ Fatal ☐ Recovered with sequelae ☐ Unknown

C. SUSPECTED MEDICATION(S)

S.No	8. Name (Brand/Generic)	Manufacturer (if known)	Batch No. / Lot No.	Exp. Date (if known)	Dose used	Route used	Frequency (OD, BD etc.)	Therapy dates		Indication	Causality Assessment
								Date started	Date stopped		
i											
ii											
iii											
Iv											

S.No as per C	9. Action Taken (please tick)						10. Reaction reappeared after reintroduction (please tick)			
	Drug withdrawn	Dose increased	Dose reduced	Dose not changed	Not applicable	Unknown	Yes	No	Effect unknown	Dose (if reintroduced)
i										
ii										
iii										
iv										

11. Concomitant medical product including self-medication and herbal remedies with therapy dates (Exclude those used to treat reaction)

S.No	Name (Brand/Generic)	Dose used	Route used	Frequency (OD, BD, etc.)	Therapy dates		Indication
					Date started	Date stopped	
i							
ii							
iii							

Additional Information:

D. REPORTER DETAILS

16. Name and Professional Address:_____
_____
Pin:_____E-mail_____
Tel. No. (with STD code)_____
Occupation:_____ Signature:_____

17. Date of this report (dd/mm/yyyy):

Confidentiality: The patient's identity is held in strict confidence and protected to the fullest extent. Programme staff is not expected to and will not disclose the reporter's identity in response to a request from the public. Submission of a report does not constitute an admission that medical personnel or manufacturer or the product caused or contributed to the reaction.

Annexure V

CLINICAL TRIALS REGISTRY - INDIA
ICMR - National Institute of Medical Statistics

PDF of Trial
CTRI Website URL - http://ctri.nic.in

Clinical Trial Details (PDF Generation Date :- Tue, 18 Apr 2023 10:43:12 GMT)

CTRI Number	CTRI/2022/08/044978 [Registered on: 26/08/2022] - **Trial Registered Prospectively**
Last Modified On	25/08/2022
Post Graduate Thesis	Yes
Type of Trial	Interventional
Type of Study	Drug
Study Design	Randomized, Parallel Group, Active Controlled Trial
Public Title of Study	Effect of BooZLiv in patients with alcoholic liver disease
Scientific Title of Study	Safety and efficacy of BooZLiv in patients with alcoholic liver disease : An open-label, randomized controlled trial

Secondary IDs if Any

Secondary ID	Identifier
NIL	NIL

Details of Principal Investigator or overall Trial Coordinator (multi-center study)

Details of Principal Investigator	
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Source of Monetary or Material Support

Source of Monetary or Material Support
> MMC Pharmaceuticals Ltd

Primary Sponsor

Primary Sponsor Details	
Name	MMC Pharmaceuticals Ltd
Address	No.113, Visalakshi St, Devikarumariamman Nagar, Valasaravakkam, Chennai, Tamil Nadu 600087
Type of Sponsor	Pharmaceutical industry-Indian

Details of Secondary Sponsor

Name	Address
NIL	NIL

Countries of Recruitment

List of Countries
India

Sites of Study

Name of Principal Investigator	Name of Site	Site Address	Phone/Fax/Email
DR Rajesh N A	SRM Medical College Hospital Research Centre	Department of Gastroenterology, Medical Gastroenterology,4th floor Kancheepuram TAMIL NADU	9629006644 rajesha@srmist.edu.in

Details of Ethics Committee

Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
SRM Medical college hospital and research center	Approved	25/03/2022	No

Regulatory Clearance Status from DCGI

Status	Date
Not Applicable	No Date Specified

Health Condition / Problems Studied

Health Type	Condition
Patients	Alcoholic liver disease, unspecified

Intervention / Comparator Agent

Type	Name	Details

Inclusion Criteria

Inclusion Criteria	
Age From	18.00 Year(s)
Age To	60.00 Year(s)
Gender	Both
Details	1.Adults aged over 18 years with the evidence of alcoholic liver disease (ALD) based on a thorough history, physical examination, and laboratory tests and all of the following: 2.Chronic alcohol intake, Identified with AUDIT(Alcohol Use Disorder Inventory Test) Questionnaire 3.Active alcohol use until 4 weeks prior to presentation 4.ALT and AST elevated >1.5 times the upper limit of normal Over 1.5 ratio of AST to ALT

Exclusion Criteria

Exclusion Criteria	
Details	1.Severe alcoholic hepatitis with cirrhosis 2.Severe renal impairment 3.Participants with active viral hepatitis 4.Pregnant, attempting to conceive, or lactating women

Method of Generating Random Sequence	Computer generated randomization
Method of Concealment	Sequentially numbered, sealed, opaque envelopes
Blinding/Masking	Not Applicable

Primary Outcome

Outcome	Timepoints
Liver function test Complete blood count Prothrombin time MELD Score	baseline to 30th day ,60th day and 90th day

Secondary Outcome

Outcome	Timepoints
Adverse events SF-12 Questionnaire	After the completion of treatment

Target Sample Size	**Total Sample Size=**60 **Sample Size from India=**60 **Final Enrollment numbers achieved (Total)=**Applicable only for Completed/Terminated trials **Final Enrollment numbers achieved (India)=**Applicable only for Completed/Terminated trials
Phase of Trial	Phase 4
Date of First Enrollment (India)	01/09/2022
Date of First Enrollment (Global)	No Date Specified
Estimated Duration of Trial	**Years=**0 **Months=**9 **Days=**0
Recruitment Status of Trial (Global)	Not Applicable
Recruitment Status of Trial (India)	Not Yet Recruiting
Publication Details	Not applicable

Brief Summary

I.INTRODUCTION

•BooZLivTM is herbal oral formulation can be given as a supplemental therapy in patients with alcoholic liver disease.

•The Herbal extracts of this oral formulation has Anti oxidant, Hepatoprotective and appetite stimulating properties ; improves the liver function and overall health status of the patients

• *Pimpenella anisum (Anise)* used for the reduction of anasarca and ascites of hepatic origin, and also for the treatment of chronic, enlarged, liver.

• *Aegle marmelos (vilvam)* is popularly used as a cardiotonic, it is also considered to be useful in the treatment of liver disorders.

•*Phyllanthus niruri (Keezhanelli)* is considered to be useful as a stomachic, choleretic and also for the control of nausea and vomiting.

•This formulation has also been reported to protect the liver against hepatotoxins such as alcohol, CCl4 and other heavy metals.

JUSTIFICATION FOR THE STUDY :

•Long-term excess alcohol exposure leads to alcoholic liver disease (ALD)-a global health problem without effective therapeutic approach.

•ALD is increasingly considered as a complex and multifaceted pathological process, involving oxidative stress, inflammation and excessive fatty acid synthesis.

•The use of alternative medicine such as herbal medicines, phytonutrients, ayurvedic products and nutraceuticals used widely by the majority of the patients for various health challenges around the world.

•An estimation of 80 % of the world population depends on herbal products s first line therapy for the illness.