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A STUDY TO EVALUATE THE SAFETY AND EFFICACY OF 'DOTSHOT' IN THE TREATMENT OF HANGOVER DUE TO ALCOHOL INTOXICATION

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ABSTRACT

Background: The medical term "Hang over" literally means "collection of symptoms that directly result from the over consumption of alcohol." In chemistry, an alcohol is any organic compound in which the hydroxyl functional group (–OH) is bound to a saturated carbon atom. Alcohol in its own form is not actually toxic to our bodies, nor does it cause hangovers. The actual cause of a hangover is a toxic compound called acetaldehyde, which alcohol is converted into during detoxification. **Objectives:** Study to evaluate the safety and efficacy of health drink 'DOTSHOT', A product of K patel Phyto Extractions Pvt. Ltd. in the treatment of hangover due to alcohol intoxication. **Conclusion**: Dotshot beverage increased ALDH activity, helping to metabolize / breakdown of the alcohol quickly and it shows the greatest increased ALDH activity and breakdown of acetaldehyde and promotes efficient acetaldehyde to cure the mild hangover. Also the subjects who were dosed with Test Product i.e., Dotshot had lower Blood Aldehyde Levels at 10 hours. So, this proves that DOTSHOT is safer, efficient and superior in alleviating the Alcohol induced hangover symptoms by increasing ALDH activity leading to the increase in the phase II detoxification of Alcohol.

KEYWORDS: Acetaldehyde dehydrogenase (ALDH), Alcohol dehydrogenase (ADH), Dot shot.

INTRODUCTION

Alcohol

In chemistry, an alcohol is any organic compound in which the hydroxyl functional group (–OH) is bound to a saturated carbon atom.

Alcohol in its own form is not actually toxic to our bodies, nor does it cause hangovers. The actual cause of a hangover is a toxic compound called acetaldehyde, which alcohol is converted into during detoxification.

There are two phases of detoxification.

The first phase converts alcohol into the intermediary metabolite, acetaldehyde.

The second phase tags this metabolite so that it can be excreted from the body as a water soluble molecule, acetic acid.

Unfortunately, this second phase is slower than the first, and acetaldehyde actually gets backed up in a line-up, waiting to be excreted from our bodies. When we wake up, this build-up is what causes us to feel like garbage.

Causes of Hangover

Hangovers are caused by excessive alcohol consumption. For some, a single alcoholic beverage can trigger headache while some drink heavily and yet escape a hangover. There are many factors which contribute to the causation of a hangover these include.

- Alcohol is a diuretic and causes the body to produce more urine. This can lead to dehydration which can be indicated by thirst, dizziness or light-headedness.
- Alcohol causes an inflammatory response by the

immune system. This inflammatory reaction affects appetite, memory and sleep. It also causes dilation of blood vessels leading to a severe headache.

- Alcohol irritates the lining of the stomach increasing the production of stomach acids. This reduces the rate of stomach emptying which in turn can contribute to nausea, vomiting and pain in the stomach.

- Alcohol intake can also lead to low blood sugar as it adds stress on the liver, reducing the glucose production. Glucose is the fuel required for all cells, especially the brain cells.

- Indirect effects of alcohol are due to acetaldehyde which is formed when your liver metabolizes alcohol. Acetaldehyde acts like a drug making you sweat, flush and increasing your heart rate. Excess acetaldehyde accumulation can lead to vomiting.

Alcohol can decrease sleep and make one feel groggy and tired. This is another indirect effect of alcohol.

Symptoms: Symptoms of a hangover typically begin the morning after the night a session of heavy drinking, when the level of blood alcohol is almost zero. Depending upon the quantity of alcohol you drink, you can experience any of the following symptoms.

- Fatigue or exhaustion
- Increased thirst
- Severe headaches
- Muscle aches and pains
- Nausea, vomiting and stomach ache
- Poor sleep
- Dizziness or sensation as if everything is spinning around
- Trembling
- Bloodshot eyes
- Increased salivation
- Inability to concentrate
- Mood disturbances such as anxiety, irritability and depression
- Rapid heartbeat

If any person shows the following signs and symptoms, they may have alcohol poisoning. This is a medical emergency requiring immediate treatment and care.

- Irregular breathing rhythm
- Breathing slows down
- Person goes into a daze
- Seizures
- Drastic fall of body temperature
- Person loses consciousness
- Skin becomes pale or bluish
- Vomiting continuously

The intensity of a hangover is closely related to the amount of alcohol intake and the amount of sleep a person is able to get after drinking alcohol. The lesser the duration of sleep, the greater is the intensity of hangover symptoms. There is no safe limit of alcohol which can be consumed to prevent a hangover. Hangover occurrence depends upon a number of factors like how much sleep the person had, how tired the person was prior to drinking and how much water the individual drank during the drinking session.

Description

Curcumin is a symmetric molecule, also known as diferuloyl methane.Curcumin is known for its antioxidant, anti-inflammatory, antiviral, antibacterial, antifungal, and cancer chemo-preventive actions. Curcumin exhibits hypolipidemic activities and has also been studied extensively as a chemo-preventive agent in several cancers. Additionally, it has been suggested that curcumin may contribute in part to the lower rate of colorectal cancer in Asian countries compared to rates in other countries.

Objectives

Primary Objective

To assess the efficacy of Health drink DOTSHOT 70 ml as compared to PLACEBO in the people with hangover.

Secondary Objective

To assess the safety of Health drink DOTSHOT 70 ml as compared to PLACEBO in patients with hangover.

METHODS

Inclusion Criteria

Healthy male between age 25-45 years, have the willingness to undergo alcohol drinking and able to comply with all trial requirements were included in the study. Patients who has Michigan Alcoholism Screening Test (MAST): more than 2 to 5 and willing to provide written informed consent for participation in the study and adhere to the protocol requirements.

Exclusion Criteria

Patients having a medical history of significant hypersensitivity or allergic reaction to turmeric or related products. Volunteers have history of alcohol toxicity like liver cirrhosis, neurological disease, peptic disease, diabetes, drug abuse. Volunteers have undergone any concomitant medications like antibiotics, anticoagulants, tricyclic antidepressant, cardiovascular medication, sedative, hypnotics. Prior to 14 days.History of bile duct obstruction or Cysts of the common bile duct. If they have hypersensitivity for alcohol ingestion. If they have habit of smoking or tobacco chewing.

Study was conducted by randomized, Double Blind, parallel group, placebo controlled clinical study by ICBio Clinical Research Pvt. Ltd. It involved in the clinical attendance of the subjects on recruitment and on follow –up. Subjects enrolled in the study received Study drug (from Baseline visit to 02 days – 70 ml of Health drink of DOTSHOT 30 minutes after last drink. The safety and efficacy parameters were compared with baseline and follow-up data with laboratory

investigations, demographics were analyzed in the study. Adverse events / side effects were noted for each follow-up visits.

Ethics Committee Approval

All study related documents Protocol, Case Report Form, Dairy card, Investigator Brochure and Informed Consent Documents (English and Kannada Versions). Written Informed Consent was obtained from the subjects before the start of the trial and after due approval from IEC/IRB. Ethics Committee notifications as per the GCP guidelines issued by Central Drugs Standard Control Organization and Ethical guidelines for biomedical research on human subjects issued by Indian council of Medical Research has been followed during the Conduct of the Study (Clinical IEC-Institutional Ethics Committee for Ethics in Research and Approved on 09th Sep 2016).

Study Outcomes

Primary Outcomes

- Assessment of changes in Biochemical Evaluation from screening to end of the treatment for hangover effects.
- The Biochemical parameters includes

➢ ALDH (Acetaldehyde Dehydrogenase): Baseline, after 0, 2 hours and 10 hours of the formulation.
➢ Blood Aldehyde: Baseline, after 0, 2 hours and 10 hours of the formulation.
➢ Blood Alcohol: Baseline, after 0, 2 hours and 10 hours of the formulation.
➢ ALT, AST and ALP (baseline, 2 and 10 hours of formulation)

- Efficacy of drug.

Secondary Outcomes

- Assessment of Changes in the Behaviour from screening to end of the treatment for hangover effects.
- Behaviour study based questions:

➢ Symptoms questionnaires to understand the level of hangover.
➢ Walk test on drawn single line on the floor (15 meters) to understand the level of hangover

- Incidence and rate of adverse events
- Safety Concern of the Drug

Disposition of Subjects

Total of 30 subjects
Drug A: Health drink of 70 ml of K. Patel Phyto extraction Pvt. Ltd. (DOTSHOT) 30 minutes after last drink. (15 subjects)
Drug B: Health drinks of 70 ml of PLACEBO (without active constituents) 30 minutes after last drink**.** (15 subjects).

Visit Details

The patients were screened and enrolled. The enrollment day was considered as the baseline Day and the patient were in house till end of treatment visit on Day 2.

Statistical Analysis

Data Analysis was carried out using 5% significance level and 80 % power for study using SAS. The difference within the group will be assessed using paired t-test.

RESULTS

In the study 30 patients were screened and enrolled after meeting the inclusion Criteria and they are Randomised randomly into Drug A and Drug B. The enrolled subjects consisted of Healthy male.

Data Sets Analyzed

Table. 1: Data sets analyzed for the test and placebo treatments.

Treatments	Placebo	Investigational Product
Enrolled	15	15
Randomized	15	15
No. of patients completed visit	15	15
Withdrawn	0	0

Efficacy Evaluation

Primary Endpoints: Primary endpoints taken under consideration were Alanine amino transferase (ALT), Aspartate aminotransferase (AST), Alkaline phosphatase (ALP), ALDH (Acetaldehyde Dehydrogenase), Blood Aldehyde and Blood Alcohol. A descriptive demonstration on the efficacy evaluation for all the above mentioned biochemical parameters are presented below

Alanine amino transferase (ALT)

Mean Alanine amino transferase from the screening to EOT: The mean, mean change of Alanine amino transferase level from baseline i.e., screening, 0 hours, 2 hours and 10 hours in the Supplement -A and Supplement-B are represented in the below tables & figures.

Changes from baseline to zero (0 hours) was not reported as the values were almost similar in baseline and zero (0 hours).

Table. 02: MeanAlanine amino transferase (ALT)levelat screening and EOT.

Groups	Baseline (N=30)	2 Hours (N=30)	10 hours
Supplement A	46.27± 9.87	39.20± 11.11	42.07± 5.07
Supplement B	41.53± 10.43	38.80±8.55	40.80±8.74

Table. 03: Mean Change in Alanine amino transferase (ALT) level from screening to EOT.

Group	Baseline to 2 hours	Baseline to 10 hours
Supplement A	-7.067	-4.200
Supplement B	-2.733	-0.733

Table. 04: 95% Confidence Interval and p-values for Mean Change in Alanine amino transferase (ALT) level from screening to EOT.

Paired **T-TEST** **VAR: Alanine Amino Transferase (ALT)**						
Group	**95% Confidence Interval for Mean**					
	Baseline to 2 hours		**p-value**	**Baseline to 10 hours**		**p-value**
Supplement A	-1.741	7.0412	0.0130	-8.611	0.2114	0.0605
Supplement B	-6.848	1.3814	0.1761	-4.848	3.3814	0.7080

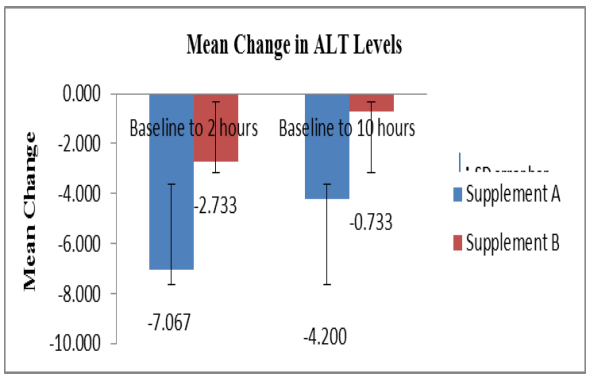


Figure. 1.

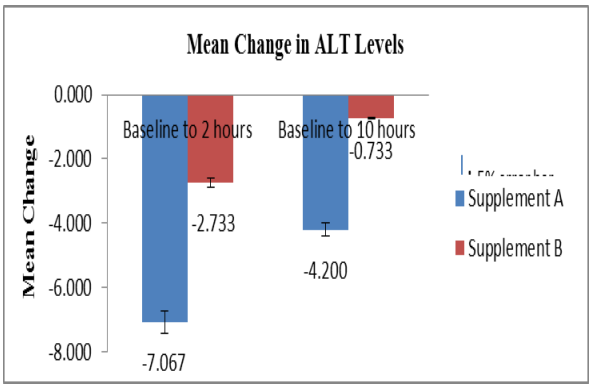


Figure. 2.

Aspartate aminotransferase (AST)

Mean Aspartate aminotransferase from the screening to EOT: The mean, mean change of Aspartate aminotransferaselevel from baseline i.e., screening, 0 hours, 2 hours and 10 hours in the Supplement-A and Supplement-B are represented in the below tables & figures.

Changes from baseline to zero (0 hours) was not reported as the values were almost similar in baseline and zero (0 hours).

Table. 05: MeanAspartate aminotransferase (AST) level at screening and EOT.

Groups	Baseline (N=30)	2 Hours (N=30)	10 hours
Supplement A	24.07 ± 5.30	25.67 ± 9.80	25.20 ± 7.56
Supplement B	24.73 ± 10.56	22.87 ±9.26	24.40 ±8.08

Table. 06: Mean Change in Aspartate aminotransferase (AST) level from screening to EOT.

Group	Baseline to 2 hours	Baseline to 10 hours
Supplement A	1.60	1.13
Supplement B	-1.87	-0.33

Table. 07: p-values for Mean Change in Aspartate aminotransferase (AST) level from screening to EOT using Wilcoxon-Rank Sum Test.

Wilcoxon Rank-Sum Test Var: Aspartate Aminotransferase (Ast)				
Group	**Baseline to 2 hours**	**p-value**	**Baseline to 10 hours**	**p-value**
Supplement A		0.5000		0.4021
Supplement B		0.2602		0.2211

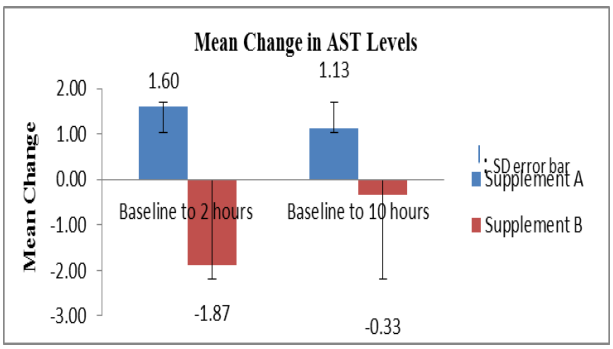


Figure 3

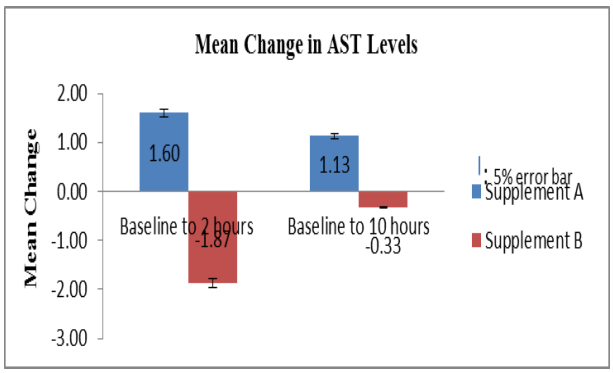


Figure 4

Alkaline phosphatase (ALP)

Mean Alkaline phosphatase from the screening to EOT: The mean, mean change of Alkaline phosphataselevel from baseline i.e., screening, 0 hours, 2 hours and 10 hours in the Supplement -A and Supplement-B are represented in the below tables & figures: Changes from baseline to zero (0 hours) was not reported as the values were almost similar in baseline and zero (0 hours).

Table. 08: MeanAlkaline phosphatase (ALP) level at screening and EOT.

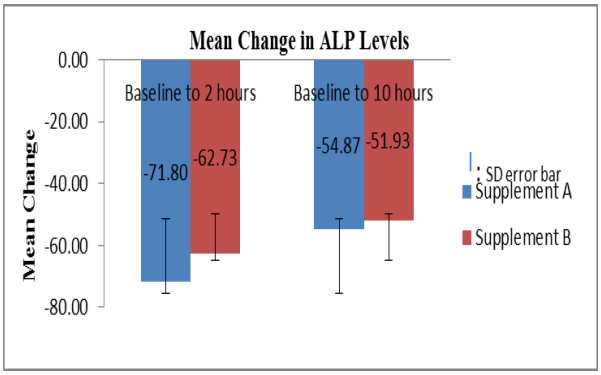
Groups	Baseline (N=30)	2 Hours (N=30)	10 hours
Supplement A	92.47± 17.15	20.67± 7.93	37.60± 6.20
Supplement B	83.93± 23.67	21.20±7.06	32.00±5.50

Table 09: Mean Change in Alkaline phosphatase (ALP) level from screening to EOT

Group	Baseline to 2 hours	Baseline to 10 hours
Supplement A	-71.80	-54.87
Supplement B	-62.73	-51.93

Table. 10: 95% Confidence Interval and p-values for Mean Change in Alkaline phosphatase (ALP) level from screening to EOT.

PAIRED T-TEST VAR: ALKALINE PHOSPHATASE (ALP)						
Group	**95% Confidence Interval for Mean**					
	Baseline to 2 hours		**p-value**	**Baseline to 10 hours**		**p-value**
Supplement A	-78.58	-65.02	<.0001	-64.77	-44.96	<.0001
Supplement B	-74.47	-50.99	<.0001	-65.28	-38.59	<.0001



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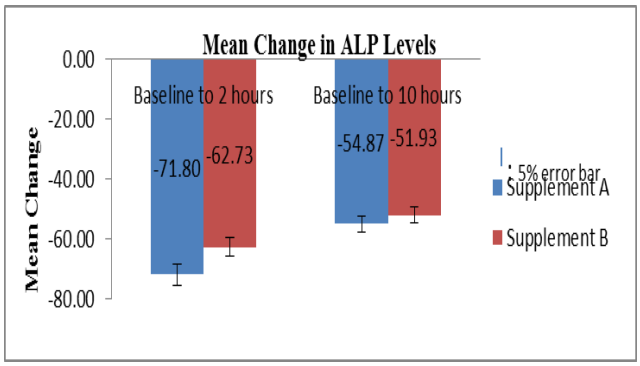


Figure. 6.

ALDH (Acetaldehyde Dehydrogenase)

Mean Acetaldehyde Dehydrogenase from the screening to EOT: The mean, mean change of Acetaldehyde Dehydrogenaselevel from baseline i.e., screening, 0 hours, 2 hours and 10 hours in the Supplement -A and Supplement-B are represented in the below tables & figures: Changes from baseline to zero (0 hours) was not reported as the values were almost similar in baseline and zero (0 hours).

Table. 11: MeanALDH (Acetaldehyde Dehydrogenase) level at screening and EOT.

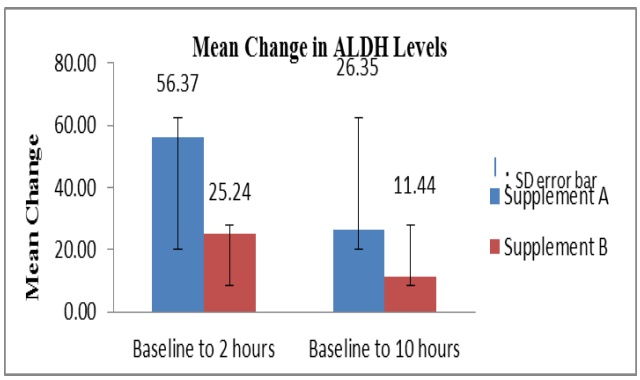
Groups	Baseline (N=30)	2 Hours (N=30)	10 hours
Supplement A	62.47 ± 3.27	118.83± 12.34	88.82± 5.40
Supplement B	62.93± 4.57	88.17± 7.13	74.37±5.11

Table. 12: Mean Change in ALDH (Acetaldehyde Dehydrogenase) level from screening to EOT.

Group	Baseline to 2 hours	Baseline to 10 hours
Supplement A	56.37	26.35
Supplement B	25.24	11.44

Table. 13: 95% Confidence Interval and p-values for Mean Change in ALDH (Acetaldehyde Dehydrogenase) level from screening to EOT.

PAIRED **T-TEST** **VAR: Acetaldehyde Dehydrogenase (ALDH)**						
Group	**95% Confidence Interval for Mean**					
	Baseline to 2 hours		**p-value**	**Baseline to 10 hours**		**p-value**
Supplement A	48.828	63.905	<.0001	23.257	29.451	<.0001
Supplement B	21.124	29.353	<.0001	7.666	15.204	<.0001



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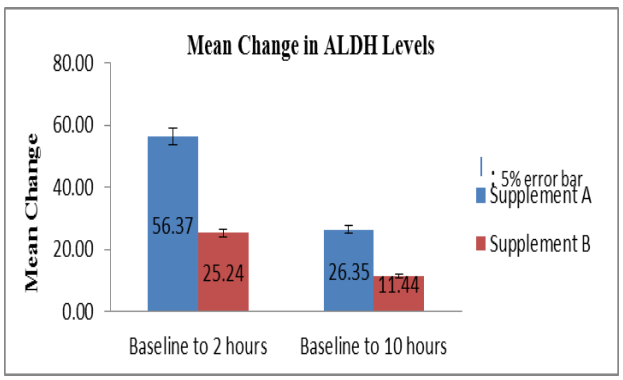


Figure. 8.

Blood Aldehyde

Mean Blood Aldehyde from the screening to EOT

The mean, mean change of Blood Aldehyde level from baseline, 0 hours, 2 hours and 10 hours in the Supplement -A and Supplement B are represented in the below tables & figures: Changes from baseline to zero (0 hours) was not reported as the values were almost similar in baseline and zero (0 hours).

Table. 14: MeanBlood Aldehyde level at screening and EOT.

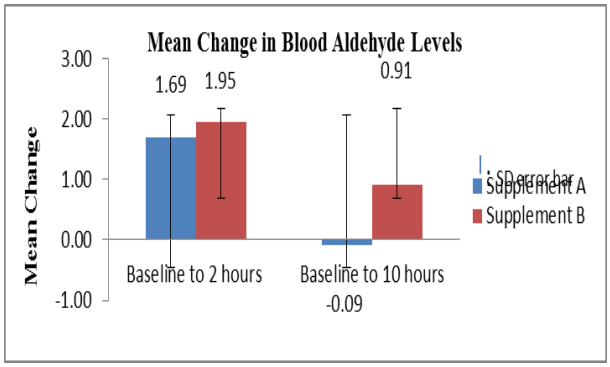
Groups	Baseline (N=30)	2 Hours (N=30)	10 hours
Supplement A	1.48 ± 0.36	3.17 ± 0.15	1.39 ± 0.35
Supplement B	1.57 ± 0.26	3.51 ± 0.25	2.47 ± 0.24

Table. 15: Mean Change in Blood Aldehydelevel from screening to EOT.

Group	Baseline to 2 hours	Baseline to 10 hours
Supplement A	1.69	-0.09
Supplement B	1.95	0.91

Table. 16: p-values for Mean Change in Blood Aldehydelevel from screening to EOT.

WILCOXON RANK-SUM TEST VAR: BLOOD ALDEHYDE				
Group	**Baseline to 2 hours**	**p-value**	**Baseline to 10 hours**	**p-value**
Supplement A		<.0001		0.0874
Supplement B		<.0001		0.1792



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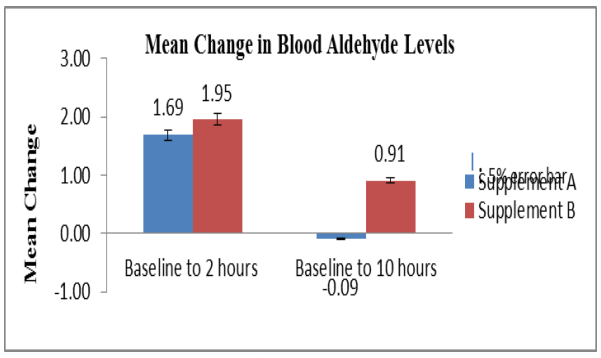


Figure 10.

Blood Alcohol

Mean Blood Alcohol from the screening to EOT: The mean, mean change of Blood Alcohollevel from baseline ,0 hours, 2 hours and 10 hours in the Supplement-A and Supplement-B are represented in the below tables & figures: Changes from baseline to zero (0 hours) was not reported as the values were almost similar in baseline and zero (0 hours).

Table. 17: MeanBlood Alcohol level at screening and EOT .

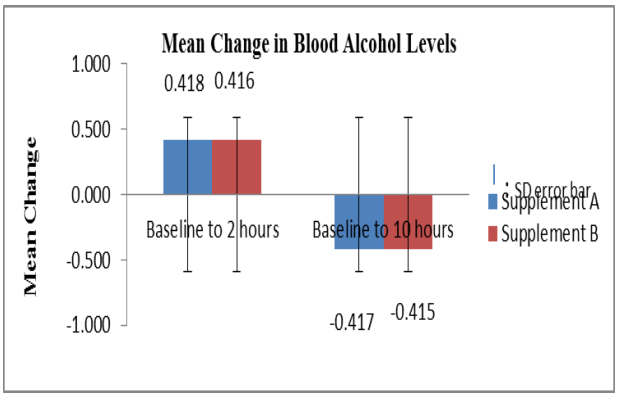
Groups	Baseline (N=30)	2 Hours (N=30)	10 hours
Supplement A	0.0019± 0.0008	0.4193± 0.0608	0.0027± 0.0015
Supplement B	0.0024± 0.0011	0.4180± 0.0517	0.0033± 0.0016

Table. 18: Mean Change in Blood Alcohol level from screening to EOT.

Group	Baseline to 2 hours	Baseline to 10 hours
Supplement A	0.418	-0.417
Supplement B	0.416	-0.415

Table 19: p-values for Mean Change in Blood Alcohol level from screening to EOT

WILCOXON RANK-SUM TEST VAR: BLOOD ALCOHOL				
Group	**Baseline to 2 hours**	**p-value**	**Baseline to 10 hours**	**p-value**
Supplement A		<.0001		0.0550
Supplement B		<.0001		0.0500



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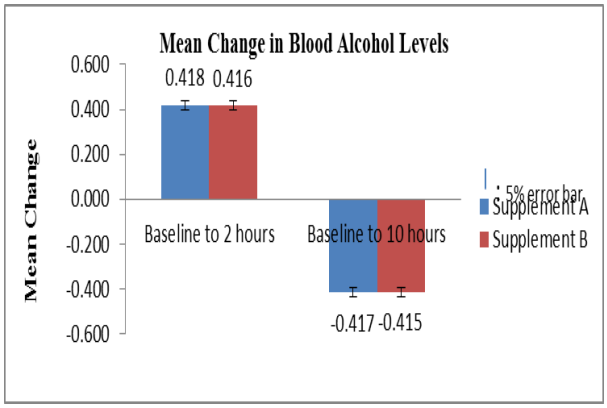
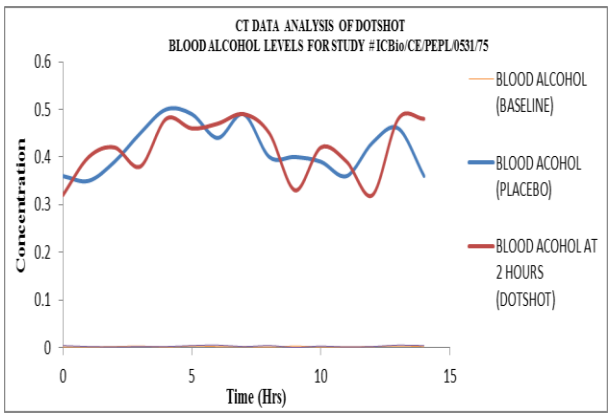


Figure 12.

A graphical analysis of the data for Blood Aldehyde and Blood Alcohol were made to compare the efficacy of Supplement-A (Dotshot) health drink with Supplement-B(Placebo).



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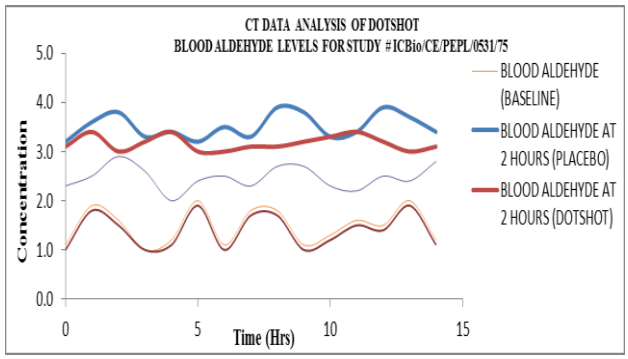

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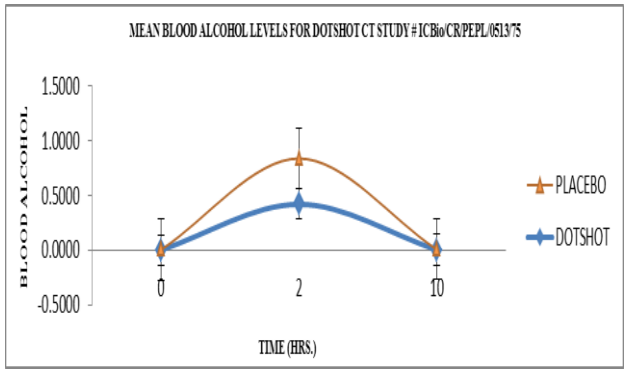

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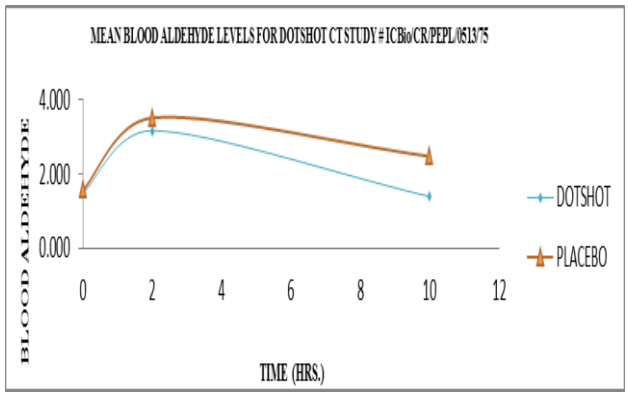

Figure. 16.

The above mentioned figures are throwing clear indication that Dotshot is more efficacious in decreasing Blood Aldehyde Levels that would lead to Hangover symptoms.

Secondary Endpoints

Secondary parameters considered in the study for comparing the efficacy between Supplement (A) – Dot shot and Supplement (B) – Placebo were Questionnaire to ask to understand the level of hangover

and Walk test on drawn single line on the floor (15 meters) to understand the level of hangover.

Frequency distribution was used to compile the scores with their interpretations for Questionnaire to ask to understand the level of hangover and Walk test to understand the level of hangover.

Frequency Distribution of Questionnaire for Hangover for Test (A) & Placebo (B).

Level of Hangover				
Level_of_Hangover	**Frequency**	**Percent**	**Cumulative Frequency**	**Cumulative Percent**
Mild Hangover	14	46.67	14	46.67
Moderate hangover	1	3.33	15	50.00
No Hangover	15	50.00	30	100.00

Randomization	Level of Hangover	Frequency Count	Expected Frequency Under Independence	Percent of Total Frequency
A	Mild Hangover	1	7.0	3.3333
	Moderate hangover	0	0.5	0.0000
	No Hangover	14	7.5	46.6667
B	Mild Hangover	13	7.0	43.3333
	Moderate hangover	1	0.5	3.3333
	No Hangover	1	7.5	3.3333

As per above mentioned Frequency Table of "Questionnaire For Hangover" out of 15 subjects only 1 subject was found to have Mild Hangover and 14 subjects were reported for No Hangover for Supplement (A) – Dotshot whereas for Supplement (B) – Placebo out of 15 subjects, 13 subjects reported for Mild hangover, 1 subject for Moderate Hangover and 1 subject for No Hangover.

Frequency Distribution for Level of Hangover for test (a) & placebo (b) by walk test.

Level of Hangover				
Level_of_hangover	**Frequency**	**Percent**	**Cumulative Frequency**	**Cumulative Percent**
Mild hangover	17	56.67	17	56.67
No Hangover	13	43.33	30	100.00

Randomization	Level of Hangover	Frequency Count	Expected Frequency Under Independence	Percent of Total Frequency
A	Mild hangover	3	8.5	10.0000
	No Hangover	12	6.5	40.0000
B	Mild hangover	14	8.5	46.6667
	No Hangover	1	6.5	3.3333

As per above mentioned Frequency Table of "Walk Test" out of 15 subjects only 3 subjects were found to have Mild Hangover and 12 subjects were reported for No Hangover for Supplement (A) – Dotshot whereas for Supplement (B) – Placebo out of 15 subjects, 14 subjects reported for Mild hangover and 1 subject for No Hangover.

From the above mentioned results obtained from Secondary Endpoints clearly indicates that Supplement (A) – Dotshot is much efficacious in controlling Hangover symptoms in comparison to Supplement (B) – Placebo.

Safety Evaluation

Adverse Events: No adverse events were noted during the clinical trial and it is concluded that investigational product is safe to use.

DISCUSSION AND CONCLUSION

As per the study outcomes no adverse events were observed during the clinical trial and this concludes that investigational product is safe enough to use.

The results obtained from Intra-group Statistical analyses and Efficacy analyses of Supplement (A) i.e., DOTSHOT and Supplement (B) i.e., PLACEBO, as discussed above showed that Supplement (A) -

DOTSHOT was found to be effective in increasing the ALDH (Acetaldehyde Dehydrogenase) levels and thereby decreasing the Blood Aldehyde levels which will alleviate the symptoms of hangover.

A significant reduction in Blood Alcohol and Blood Aldehyde levels were also observed with DOTSHOT in comparison to Placebo.

Alanine amino transferase (ALT), Aspartate aminotransferase (AST) and Alkaline phosphatase (ALP) levels were found to be within normal clinical range in both the treatment groups but a significant reduction in liver enzymes were observed with DOTSHOT.

From study results it's evident that DOTSHOT is helpful in reducing the liver enzymes which shows the liver protective property of DOTSHOT.

So, this proves that DOTSHOT is safer, efficient and superior in alleviating the Alcohol induced hangover symptoms in comparison to PLACEBO by increasing ALDH activity leading to the increase in the phase II detoxification of Alcohol.

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