

ALCOTOX IN VIVO HUMAN STUDY – High Level summary results Executed: 4Q 2021

The Alcotox *In Vivo* human study was executed through the 4th quarter of 2021 led by Dr. Kyle Hoedebecke based out of Houston, Texas (USA). The study was comprised of 70 participants with an evaluation of both short term changes in liver functions tests as well subjective hangover symptoms following high levels of alcohol/acetaldehyde exposure. The highlights of the study and the significant outcomes are highlighted and explained below.

There are two main liver function enzymes, AST and ALT.

AST / GOT

AST (Aspartate Aminotransferase) is also known as GOT (serum glutamic-oxaloacetic transaminase). and is a protein made by liver cells. When liver cells are damaged, AST leaks out into the bloodstream and the level of AST in the blood becomes elevated. AST is also found in parts of the body other than the liver - including the heart, kidneys, muscles, and brain. Elevated AST levels indicate that cells in any of these parts of the body are damaged.

ALT / GPT

ALT (Alanine transaminase) is also known as GPT (serum glutamate-pyruvate transaminase). ALT is found mainly in the liver. High ALT levels are indicative of a liver injury.

FATTY LIVER AND CIRRHOSIS

High levels of AST and/or ALT correspond with some type of liver damage. A normal AST:ALT ratio should be <1. In patients with fatty liver disease the AST:ALT ratio is >1 and often >2 for those with alcoholic liver disease including cirrhosis.

STUDY RESULTS

When drinking alcohol, the underlying causal factor for elevated levels of these liver function enzymes is acetaldehyde. It also contributes to alcohol addiction and hangovers. The central and key focus of Alcotox is to reduce acetaldehyde. With this focus in mind, we see marked improvements in the values of these key liver function enzymes. Results of the executed study are shown below.

AST / GOT

Alcotox was shown to significantly reduce the level of AST / GOT from baseline reading of 38.37 to 31.88.

ALT / GPT

Alcotox was shown to significantly reduce the level of ALT / GPT from baseline reading of 33.68 to 28.80.

HANGOVER SYMPTOMS

A major underlying causal factor for hangovers is also acetaldehyde. Alcotox was shown to significantly reduce hangover rates. Only 13.6% of those in the Alcotox group experienced any hangover symptoms. On the contrary, 65.4% of those who didn't use Alcotox had a hangover.

CONCLUSION

Alcotox demonstrated a significant improvement of key liver function enzymes upon testing after heavy alcohol ingestion. Whereas those who drank without Alcotox had a worsening of their liver lab values, the group who used Alcotox actually saw an *improvement* in liver lab values.

Test results were in-line and exceeded expectations. A 3 month study in the medium to longer term is intended to evaluate longer term positive impacts of Alcotox on liver function and other biomarkers.

SYNOPSIS

Virtually all alcohol induces harm - with acetaldehyde as the primary underlying cause. Reducing acetaldehyde is the central core purpose of Alcotox.

Minimising hangover symptoms translates to a better quality of life, but more importantly, the added assurance that the acetaldehyde reducing feature of Alcotox improves liver function and mitigates the impairment of key proteins, enzymes, as well as protection against the cancer-causing effects of acetaldehyde and DNA damage.

APPENDIX: ALCOTOX IN VIVO HUMAN – STUDY DATA

The results of the Alcotox *In Vivo* human study results executed on a larger scale with 70 participants are presented below.

Test	Alcotox Used	Improved or Worsened	Before Drinking	After Drinking	Statistically Significant
AST/GOT	Yes	Improved	38.37	31.88	Yes
AST/GOT	No	Worsened	30.25	37.24	Yes
ALT/GPT	Yes	Improved	33.68	28.80	Yes
ALT/GPT	No	Worsened	29.93	38.50	Yes
Hangover symptoms	Yes	N/A	N/A	13.6%	Yes
Hangover symptoms	No	N/A	N/A	65.4%	Yes

Table of Significant Alcotox Study Results

In Vivo testing with n=>30 to establish efficacy and safety data

The conformance of the acquired variables to the normal distribution was tested using the Shapiro-Wilk test. The variables are not acceptable for the normal distribution assumption ($p < 0.05$), according to the test results. The Wilcoxon Signed Rank Test was utilized as a result.

GROUP 1: ALCOTOX CONSUMERS

Table 1: According to the GOT values measured in the pre-test and post-test, Wilcoxon Signed Rank Test.

PRE-POST	N	Average Rank	Total /Sum of Ranks	Z	p
NEGATIVE	29	23,38	678,00	-2,14	0,03
POSITIVE	15	20,80	312,00		
EQUAL	0				
Total	44				

In Table 1, there is a significant difference between the GOT pre-test and post-test values. The baseline test levels before the consumption of alcohol (Mdn=38.37) of Alcotox consumers were significantly higher than the test levels (Mdn=31.88) after drinking alcohol; $Z = -2.14$, $p < 0.05$, $r = -0.20$

Table 2: Wilcoxon Signed Rank Test according to the GPT values measured in the pre-test and post-test

PRE-POST	N	Average Rank	Total /Sum of Ranks	Z	p
NEGATIVE	33	23,76	784,00	-3,37	0,00
POSITIVE	11	18,73	206,00		
EQUAL	0				
Total	44				

There is a significant difference between the GPT values in Table 2. The baseline test levels before consuming alcohol (Mdn=33.68) of Alcotox consumers are significantly higher than the test levels (Mdn=28.80) after drinking alcohol. $Z = -3.37$, $p < 0.05$, $r = -0.32$

Table 3: According to the GGT values measured in the pre-test and post-test, Wilcoxon Signed Rank Test

PRE-POST	N	Average Rank	Total /Sum of Ranks	Z	p
NEGATIVE	19	23,76	18,05	-1,77	0,76
POSITIVE	25	18,73	25,88		
Equal	0				
Total	44				

Table 3 shows that there is no significant variation in GGT values. There was no statistically significant difference between Alcotox users' test levels (Mdn=35.89) before and after they consumed alcohol (Mdn=36.50). Test results: $Z = -1.77$, $p > 0.05$, $r = 0.16$

Table 4: the CK values measured in the pre-test and post-test, Wilcoxon Signed Rank Test

PRE-POST	N	Average Rank	Total /Sum of Ranks	Z	p
NEGATIVE	27	25,70	694,0	-2,32	0,02
POSITIVE	17	17,41	296,0		
Equal	0				
Total	44				

In Table 4, there is a considerable disparity between the CK values. There was a substantial increase between Alcotox users' test levels (Mdn=72.4) before drinking alcohol and their test levels (Mdn=89.91) after drinking alcohol. $r = 0.22$, $Z = -2.32$, $p < 0.05$

Alcotox had a significant reduction in key liver tests after heavy alcohol ingestion. Whereas those who drank without Alcotox had a worsening of their liver lab values, the group who used Alcotox had *improved* liver lab values.

Alcotox improved hangover rates. Only 13.6% of those in the Alcotox group experienced a hangover while 65.4% of those who didn't use Alcotox had a hangover.

We are planning on a 3-month study to evaluate longer term positive impacts of Alcotox on chronic alcohol abuse patients.