LIV 52 NITRO™

EFFECT OF LIVNITRO ON PROTEIN ANABOLISM

A Prospective, Randomized, Triple Blind Placebo Controlled Clinical Study

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ABSTRACT

The term 'anabolism' is defined as the building or constructive process conducted by cells in which simple substances are converted into more complex compounds. The liver is called by many to be the chief metabolic organ of the body and is thought to have an effect on the liver's performance. Recently, many natural products shoppers have sought out safe herbal supplements over commonly used testosterone based supplements for anabolic benefits. The herbal combination in LivNitro+ has been shown in previous clinical trials to promote liver cell activity and general liver function. In this study, we set out to investigate LivNitro+ to determine if it could support the creation of proteins (anabolism) and promote general liver function. Study subjects were given either LivNitro+ or the placebo at a dose of one capsule twice daily for 60 days in triple blind controlled clinical trial. The criteria for evaluation were to estimate nitrogen retention as evaluated by total nitrogen excretion (urinary, fecal, and total), serum testosterone, and serum cortisol levels.

CLINICAL SUMMARY

LivNitro+ showed a decrease in fecal and urinary nitrogen excretion thereby maintaining positive nitrogen balance (a biological marker of protein creation, retention and growth). Excretion of urinary urea was also reduced after LivNitro+ administration. No adverse effects were observed. In this study, LivNitro+ provided beneficial effects on protein anabolism in healthy individuals.

KEY WORDS

LivNitro+, Protein anabolism, Total nitrogen excretion, Anthropometric data

INTRODUCTION

Nutrition plays a central role in Ayurveda, the traditional medical system of India. Ayurveda places special emphasis on "Ahara" (diet) and "Anna" (food) as a means to good life, health and wellness. Healthy and wholesome food nourishes the mind, body and soul. Ayurveda asserts that although the digestive capacity of each person may be different, the quality and appropriate quantity of food are necessary for a healthy life.1 Food taken in proper quantity provides strength, vigor, good complexion and nurtures the health of the tissues. [2, 3]

In contrast to western dietary understanding and the US guide to diet, Ayurveda states that a diet can be vegetarian (plant-based) or non-vegetarian (animal-based) and portion size should be customized for each individual according to one's own needs, body constitution (dosha) and agni bal (digestive power). Also, the quality and properties of food should be taken into consideration such as heavy, light and oily.[1]

Anabolism (protein creation) is a set of metabolic processes that uses the energy released by catabolism (tissue destruction as often seen in weight lifting exercises) to create complex molecules. The production of precursors such as amino acids, monosaccharides, isoprenoids and nucleotides, their activation into reactive forms using energy from ATP, and thirdly, the assembly of these precursors into complex molecules such as proteins, polysaccharides, lipids and nucleic acids contribute to anabolism. Factors like caloric intake, digestion, absorption, utilization and endocrine functioning all influence anabolism.

Several recent publications indicate that the maximum stimulation of muscle protein fractional synthetic rate occurs with intake of 20 to 30 grams of protein. This finding has led to the concept that there is a maximal anabolic response to protein intake with a meal. Higher protein intakes when protein synthesis is maximized are characterized by suppressed protein breakdown and via that mechanism lead to a greater anabolic response. This explains why when net protein synthesis is measured, the relationship between amino acid availability and net gain remains linear, without any apparent plateau of effect at higher levels of availability.[4]

The liver being an important metabolic center has a definite role to play in anabolic processes. Various natural products are known to have a supportive effect and influence on the hepatic parenchyma. The commonly used ones for anabolic benefits are testosterone promoters. The ergogenic effects associated with them include increases in lean body mass, increase in muscle cross-sectional area, decrease in body fat percent, increases in muscle strength & power and increase in pain tolerance and behavior modification.[5]

However, there are several systemic adverse affects exist with the use of anabolic steroids like chances of liver tumors, testicular atrophy, changes in lipid profile and also psychological impacts; some of which are irreversible6. Moreover, anabolic steroids are banned in numerous countries by legislation for the safety concerns.

Many herbal ingredients are potent anabolic promoters known to support appetite and rate of nutrient absorption with many supplements already commercially available; however, these supplements are often promoted without conclusive research demonstrating their efficacy[7]. A recent review of 250 commercially advertised supplements found only 6 had been examined in randomized, placebo controlled studies greater than 3 weeks in duration8.

Extracts of the LivNitro+ capsule are known to act by supporting general liver function. In addition, LivNitro+ supports absorption and utilization of food and promotes bowel movements, digestion and assimilation processes.

AIM OF THE STUDY

To study the efficacy and safety of the role of LivNitro+ in protein anabolism.

MATERIALS AND METHODS

INCLUSION CRITERIA

Seventy healthy male and female volunteers, aged between 18 and 40 years of age willing to participate in the clinical study and follow the study procedures were included in the study.

EXCLUSION CRITERIA

Subjects with severe metabolic disorders, a known history or present condition of allergic response to similar pharmaceutical products, its components or ingredients in the test products, pre-existing systemic disease necessitating long-term medications, genetic and endocrinal disorders were excluded from the study. Subjects who had participated in a similar clinical investigation in the past four weeks, or used a similar product in the past four weeks, and pregnant and lactating women were excluded from the study.

STUDY DESIGN

Seventy subjects were included in the study and randomized equally into LivNitro+ capsules group and placebo group in the triple blind design where neither the investigator, nor the subject or sponsor (except for one person, the pharmacist handling the drugs) were aware of the assigned formulation.

STUDY PROCEDURE

The study protocol, CRFs, regulatory clearance documents, product related information and informed consent form were submitted to the Institutional Ethics Committee and were approved by the same. Subjects who have qualified the screening and willing to participate in the study were called for the study, and included in the study after they willingly signed informed consent. At the initial visit, a detailed medical history with special emphasis on family and past medical history was obtained from all subjects. In all subjects, a thorough systemic examination was done. All subjects were investigated by hematological and biochemical tests, to ensure the good health of the subjects. The subjects as per the randomization were advised to consume orally LivNitro+ or similar looking placebo at a dose of one capsule twice daily before meals for a period of 60 days. No vitamins or general tonics should be taken during the course of the trial. Subjects were advised to limit their calorie intake approximately to 2500-2800 cal/day (which includes regular quantity of protein).

All adverse events, either reported or observed by subjects were recorded in the CRF with information about severity, onset, duration and action taken regarding the study drug. Relation of adverse events to the study medication was predefined as "Unrelated" (a reaction that does not follow a reasonable temporal sequence from the time of administration of the drug), "Possible" (follows a known response pattern to the suspected drug, but could have been produced by the patient's clinical state or other modes of therapy administered to the patient), and "Probable" (follows a known response pattern to the suspected drug that could not be reasonably explained by the known characteristics of the patient's clinical state).

Subjects were allowed to voluntarily withdraw from the study, if they experienced serious discomfort during the study or sustained serious clinical events requiring specific treatment. For subjects withdrawing from the study, efforts were made to ascertain the reason for dropout.

STUDY FOLLOW-UP AND MONITORING

The response to therapy was evaluated by tests for nitrogen retention namely Total urinary nitrogen content, Total fecal nitrogen content and urinary urea at entry, day 9, day 18 day 28, and Day 60. Serum testosterone, serum cortisol levels were carriedout at entry, day 28 and 60.

Hematological and clinical biochemistry were done to establish the safety profile of the formulation.

PRIMARY AND SECONDARY END POINTS

Primary Objective was to evaluate the protein anabolic activity of LivNitro+ in healthy adult by maintaining a positive nitrogen balance which were measured by reduced fecal, urinary nitrogen excretion and urinary urea and improvement in the hormones responsible for protein anabolism namely serum testosterone and cortisol levels.

The secondary objective was the safety profile as incidence of adverse events and laboratory investigations including hematology as well as clinical chemistry parameters (LFT and RFT) and compliance to the study.

STATISTICAL ANALYSIS

Statistical analysis was carried out according to intention-to-treat principles. Values are expressed as Mean ± SD. Unpaired t-test for between the group analysis using two tailed p value of <0.05 was considered significant. Statistical analysis was performed using GraphPad Prism, Version 4.03 for Windows, GraphPad Software, San Diego, California, United States. www.graphpad.com

RESULTS

A total of 70 subjects were enrolled in the study. Thirty-five subjects each were randomized into LivNitro+ and placebo group. The mean age of the subjects' in the LivNitro+ group was 22.82 ± 5.11 and in the placebo group was 22.74 ± 5.18. Sex ratio was M: F 30:5 and 26:9 in LivNitro+ and placebo group respectively. (Table 1)

Baseline values of total urinary nitrogen content, fecal nitrogen content, and urinary urea are mentioned in Table 2. Total Urinary Nitrogen content in LivNitro+ group was 1.55 ± 0.51 and 1.20 ± 0.44 in placebo group with no significance between the groups at baseline. Total Fecal Nitrogen content in the LivNitro+ group was 0.98 ± 0.15 and 0.98 ± 0.12 in placebo group with no significance between the groups. Urinary urea in LivNitro+ group was 3.31 ± 1.09 and 2.60 ± 0.95 in placebo group. Statistical analysis was done using Unpaired t-test for between the group analysis using two-tailed p value.

Effect of LivNitro+ therapy on urinary nitrogen content, fecal nitrogen content and urinary urea (values presented as the difference from baseline) are mentioned in Table 3. Statistical analysis was done using Unpaired t-test for between the group analysis using two tailed p value. Total fall in Urinary Nitrogen content (Fig 2) on Day 9 as compared to baseline in LivNitro+ group was -0.01 ± 0.71 and 0.03 ± 0.63 in placebo group with no significance. On Day 18 the fall as compared to baseline in LivNitro+ group was -0.47 ± 0.52 and 0.05 ± 0.70 in placebo group with significance of p<0.0006. On Day 28 the fall as compared to baseline in LivNitro+ group was -0.13 ± 0.69 and 0.29 ± 0.41 in placebo group with significance of p<0.00032. On Day 60 the fall as compared to baseline in LivNitro+ group was -0.32 ± 0.60 and 0.06 ± 0.75 in placebo group with significance of p<0.0225.

The fall in the total Fecal Nitrogen content (Fig. 1) on Day 9 in LivNitro+ group was -0.11 ± 0.14 and 0.01 ± 0.11 in placebo group with significance of p<0.0001 between the group. On Day 18 the fall as compared to baseline in LivNitro+ group was -0.06 ± 0.17 and 0.05 ± 0.22 in placebo group with significance of p<0.0235. On Day 28 the fall as compared to baseline in LivNitro+ group was -0.08 ± 0.16 and 0.05 ± 0.18 in placebo group with significance of p<0.0027. On Day 60 fall as compared to baseline in LivNitro+ group was -0.08 ± 0.18 and 0.06 ± 0.22 in placebo group with significance of p<0.0047.

The difference in the Urinary urea level (Fig.3) on Day 9 in LivNitro+ group was -0.02 ± 1.51 and 0.14 ± 1.34 in placebo group and there was no significance between the groups. On Day 18 the fall as compared to baseline in LivNitro+ group was -0.47 ± 0.99 and 0.04 ± 1.19 in placebo group with no significance. On Day 28 the fall as compared to baseline in LivNitro+ group was -0.44 ± 1.25 and 0.41± 1.00 in placebo group with significance of p<0.0028. On Day 60 in LivNitro+ group -0.57 ± 1.46 and 0.22± 1.59 in placebo group with significance of p<0.0347.

The effect of LivNitro+ on Total nitrogen excretion are tabulated in the table 4. Total nitrogen excretion improved from 5.83±1.62 to 6.22±1.78 in LivNitro+ group at the end of 60 days. The placebo group showed improvement from 4.78±1.37 to 5.79±1.58 at the end of the study with a significance of p<0.0063 in placebo group. Total nitrogen loss was comparatively less in the LivNitro+ group as compared to the placebo which signifies anabolic effect in LivNitro+.

Total Nitrogen excretion after Normalization are provided in table 5. Total nitrogen excretion as compared to the baseline was after

RESULTS CONTINUED

normalization in LivNitro+ group at Day 9 with 0.24±1.64 which decreased further to -0.72±1.81 on day 60. In placebo group, the change was -0.31±1.65 on day 60 as compared to -0.24±1.40 on day 9. Changes were found to be significant with $p<0.0343$ in LivNitro+ group at the end of the study. This clearly indicates as compared to baseline there is a decrease in the nitrogen excretion between day 9 to day 60, which demonstrates the anabolic effect in LivNitro+.

Effect of drug therapy on endocrinal parameters are shown in Table 6. Serum testosterone levels on Day 0 in LivNitro+ group was 402.80 ± 206.50 and 335.00 ± 212.20 in placebo group with no significance. On Day 9 in LivNitro+ group was 410.20 ± 192.10 and 335.70 ± 209.60 in placebo group with no significance. On Day 60 in LivNitro+ group was 560.80 ± 265.50 and 498.70 ± 300.50 in placebo group. Though there is a trend towards increase in both the groups, but showed no significance. Serum cortisol on Day 0 in LivNitro+ group was 14.63 ± 5.70 and 15.34 ± 6.16 in placebo group with no significance. On Day 9 in LivNitro+ group was 18.59 ± 6.76 and 17.25 ± 6.38 in placebo group with no significance. On Day 60 in LivNitro+ group was 17.78 ± 4.78 and 17.33 ± 5.41 in placebo group with no significance. Statistical analysis was done using Unpaired t-test for between the group analysis using two tailed p value.

Effect of drug therapy on hematological and biochemical investigation are shown in table 7 and 8. All the values are within the normal range demonstrating the safety profile of the product.

DISCUSSION

The functional integrity of the liver is essential for nutrient supply (carbohydrates, fat, and proteins), and the liver plays a fundamental role in intermediary metabolism. For example, the liver regulates the synthesis, storage, and breakdown of glycogen, and hepatocytes express enzymes that enable them to synthesize glucose from various precursors such as amino acids, pyruvate, and lactate (gluconeogenesis).[9]

Consequently, when the liver needs support, numerous nutritional needs occur. Several factors contribute to lack of support in the liver including inadequate dietary intake of nutrients, reduction in their synthesis or absorption (less than optimized protein synthesis,), and protein loss. Because of decreased glycogen stores and gluconeogenesis[10], energy metabolism may shift from carbohydrate to fat oxidation[11] while insulin response may lag. Consequently, changes in liver function can result in a catabolic state resulting and lack of essential nutrients.[9]

The net balance between muscle protein synthesis and breakdown distinguishes the catabolic state from the anabolic state. The synthesis of new protein is derived from the intracellular pool of amino acids[12]. The intracellular pool of essential amino acids is the most important determinant of protein synthesis as the non-essential amino acids are readily available[13].

The changes in breakdown alone cannot induce a shift from the catabolic state to the anabolic state, since some of the amino acids released from protein breakdown are oxidized or transaminated and therefore not available for reincorporation into protein. On the other hand, the rate of protein breakdown will always be linked to some extent to the rate of synthesis because of the contribution of amino acids from breakdown to the intracellular pool of amino acids. Thus, when considering the role of amino acid availability in regulating the rate of muscle protein synthesis it is necessary to take account of not only the amino acids from plasma, but also the amino acids that appear in the intracellular pool as a consequence of protein breakdown.[4]

The polyherbal combination in LivNitro+ is known to promote anabolism of proteins and improve liver functions to help protein synthesis and metabolism.

Khanfar et al. isolated and identified active ingredients of Capparis spinosa as beta-sitosterylglucoside-6′-octadecanoate and 3-methyl-2-butenyl-beta-glucoside[14]. p-Methoxy benzoic acid isolated from Capparis spinosa was found to possess potent hepatoprotective activity against CCl4, paracetamol (in vivo) and in thioacetamide, galactosamine (in vitro) induced hepatotoxicity15.

Aktay et al. and Zafar et al. observed hepatoprotective effect (confirmed by histopathological examination) of Cichorium intybus against CCl4-induced hepatotoxicity and reported significant prevention of the elevation of malondialdehyde formation (plasma and hepatic) and enzyme levels (AST and ALT)[16,17].

Solanum nigrum was investigated for its hepatoprotective activity against CCl4-induced hepatic damage and Raju et al. observed remarkable hepatoprotective activity confirmed by evaluated biochemical parameters (AST, ALT, ALP and TB)[19]. Sultana et al. demonstrated that Solanum nigrum protect DNA against oxidative damage and the results suggest that the observed hepatoprotective effect of Solanum nigrum might be due to the ability to suppress the oxidative degradation of DNA in the tissue debris[18].

Upadhyay et al. identified arjunetoside, oleanolic and arjunic acids as active ingredients from Terminalia arjuna[20]. Munasinghe et al. reported potent antioxidant activity of Terminalia arjuna, which might be due to its effects on lipid peroxidation[21]. Ali et al. demonstrated that arjunaphthanoloside from Terminalia arjuna inhibits nitric oxide (NO) production[22] and terminoside A isolated from Terminalia arjuna, decreases inducible nitric oxide synthase (iNOS) levels in LPS-stimulated peritoneal macrophages[23].

Bin-Hafeez et al. showed that Cassia occidentalis modulates hepatic enzymes and provides hepatoprotection against induced immunosuppression[24]. Candan et al. and Bezic et al. reported antioxidant and antimicrobial activities of Achillea millefolium[25,26].

CONCLUSION

The results from the clinical trial demonstrates that LivNitro+ decreased the fecal and urinary nitrogen excretion thereby maintaining positive nitrogen balance. Excretion of urinary urea was also reduced after LivNitro+ administration. No adverse effects were observed and the supplement was well tolerated. The synergistic actions exhibited by the ingredients of LivNitro+ might provide the beneficial effects in protein anabolism in healthy individuals. LivNitro+ thus acts as an anabolic supporter which promotes the functional capacity of the liver and supports cellular metabolic activity and normal regeneration. Thus, the results of the study support the “Protein anabolic property” of LivNitro+.

Table 1

DEMOGRAPHIC DATA OF SUBJECTS ON ENTRY (n=70)

PARAMETERS	LIVNITRO+	PLACEBO
Number of Subjects	35	35
Age in Years (Mean ± SD)	22.82 ± 5.11	22.74 ± 5.18
SEX		
Male	30	26
Female	5	9

Table 2

BASELINE VALUES OF TOTAL URINARY NITROGEN CONTENT, FECAL NITROGEN CONTENT, AND URINARY UREA

PARAMETERS	LIVNITRO+	PLACEBO	SIGNIFICANCE
Total Nitrogen Content - Urinary g/dl	1.55 ± 0.51	1.20 ± 0.44	NS
Total Nitrogen Content - Fecal g%	0.98 ± 0.15	0.98 ± 0.12	NS
Urinary urea g/dl	3.31 ± 1.09	2.60 ± 0.95	NS

Statistical Analysis: Unpaired t-test for between the group analysis using two tailed p value.

Table 3

EFFECT OF DRUG THERAPY ON URINARY NITROGEN CONTENT, FECAL NITROGEN CONTENT, AND URINARY UREA

(values presented as the difference from baseline)

PARAMETERS	DAY	LIVNITRO+	PLACEBO	SIGNIFICANCE
Total Nitrogen Content - Urinary g/dl	Day 9	-0.01 ± 0.71	0.03 ± 0.63	NS
	Day 18	-0.47 ± 0.52	0.05 ± 0.70	p<0.0006
	Day 28	-0.13 ± 0.69	0.29 ± 0.41	p<0.0032
	Day 60	-0.32 ± 0.60	0.06 ± 0.75	p<0.0225
Total Nitrogen Content - Fecal g%	Day 9	-0.11 ± 0.14	0.01 ± 0.11	p<0.0001
	Day 18	-0.06 ± 0.17	0.05 ± 0.22	p<0.0235
	Day 28	-0.08 ± 0.16	0.05 ± 0.18	p<0.0027
	Day 60	-0.08 ± 0.18	0.06 ± 0.22	p<0.0047
Urinary urea g/dl	Day 9	-0.02 ± 1.51	0.14 ± 1.34	NS
	Day 18	-0.47 ± 0.99	0.04 ± 1.19	NS
	Day 28	-0.44 ± 1.25	0.41± 1.00	p<0.0028
	Day 60	-0.57 ± 1.46	0.22± 1.59	p<0.0347

Statistical Analysis: Unpaired t-test for between the group analysis using two tailed p value.

Table 4

EFFECT OF LIVNITRO+ ON TOTAL NITROGEN EXCRETION (g%)

	TREATMENT DAYS (MEAN ± SD)		SIGNIFICANCE
TREATMENT	Day 9	Day 60	
LIVNITRO+	5.83±1.62	6.22±1.78	NS
PLACEBO	4.78±1.37	5.79±1.58	p<0.0063

Total Nitrogen excretion (faecal + urine + urinary urea nitrogen)

Statistical analysis: paired t-test for within the group analysis using two tailed p value.

NS :Not Significant

Table 5

TOTAL NITROGEN EXCRETION AFTER NORMALIZATION (g%)

	TREATMENT DAYS (MEAN ± SD)		SIGNIFICANCE
TREATMENT	Day 9	Day 60	
LIVNITRO+	0.24±1.64	-0.72±1.81	p<0.0343
PLACEBO	-0.24±1.40	-0.31±1.65	NS

Total Nitrogen excretion (fecal +urine +urinary urea nitrogen)
Statistical analysis: paired t-test for within the group analysis using two tailed p value.
NS :Not Significant
Normalization indicates the difference from the Base line value and Day 9 /Day 60

Table 6

EFFECT OF DRUG THERAPY ON ENDOCRINAL PARAMETERS

PARAMETERS	DAY	LIVNITRO+	PLACEBO	SIGNIFICANCE
Serum testosterone ng/dl	Day 0	402.80 ± 206.50	335.00 ± 212.20	NS
	Day 9	410.20 ± 192.10	335.70 ± 209.60	NS
	Day 60	560.80 ± 265.50	498.70 ± 300.50	NS
Serum cortisol µg/dl	Day 0	14.63 ± 5.70	15.34 ± 6.16	NS
	Day 9	18.59 ± 6.76	17.25 ± 6.38	NS
	Day 60	17.78 ± 4.78	17.33 ± 5.41	NS

Statistical Analysis: Unpaired t-test for between the group analysis using two tailed p value.

Table 7

EFFECT OF DRUG THERAPY ON HEMATOLOGICAL PARAMETERS

PARAMETERS	DAY	LIVNITRO+	PLACEBO	SIGNIFICANCE
Hemoglobin	Day 0	13.96 ± 1.047	13.93 ± 1.076	NS
	Day 9	14.55 ± 1.16	14.57 ± 1.226	NS
	Day 60	14.74 ± 1.414	15.81 ± 6.431	NS
TLC count / cu.mm.	Day 0	6300 ± 1448	6257 ± 1084	NS
	Day 9	6154 ± 1284	6449 ± 1199	
	Day 60	6191 ± 1581	6057 ± 1516	NS
Granulocytes %	Day 0	55.76 ± 5.26	59.2 ± 6.37	NS
	Day 9	55.98 ± 6.61	61.39 ± 6.22	P<0.0008
	Day 60	57.39 ± 6.56	60.06± 6.25	NS
Mid %	Day 0	9.543 ± 1.68	9.289 ± 1.64	NS
	Day 9	9.523 ± 1.44	8.691± 1.73	P<0.0323
	Day 60	8.949 ± 1.68	8.657±1.81	NS
Lymphocytes %	Day 0	34.7 ± 4.75	31.51 ± 6.03	NS
	Day 9	34.5 ± 5.92	29.91 ± 5.77	P<0.0016
	Day 60	33.67 ± 6.16	31.28 ± 5.99	NS
ESR mm/h	Day 0	9.086 ± 3.17	7.486 ± 2.49	NS
	Day 9	9.429 ± 4.32	8.286 ± 2.05	NS
	Day 60	9.4 ± 3.05	9.571 ± 3.70	NS
	Day 9	86.93 ± 66.73	73.68 ± 44.05	NS
	Day 60	80.87 ± 55.82	82.42 ± 49.06	NS

Statistical Analysis: Unpaired t-test for between the group analysis using two tailed p value.

Table 8

EFFECT OF DRUG THERAPY ON CLINICAL CHEMISTRY PARAMETERS

PARAMETERS	DAY	LIVNITRO+	PLACEBO	SIGNIFICANCE
TGO-AST U/L (Aspartate transaminase)	Day 0	26.58± 13.26	23.47± 8.88	NS
	Day 9	25.54± 11.88	22.83± 8.33	NS
	Day 60	19.67± 4.78	19.46± 6.25	NS
TGP - ALT U/L (Alanine transaminase)	Day 0	29.70± 18.18	26.30± 13.10	NS
	Day 9	27.02± 14.36	24.28± 12.28	NS
	Day 60	23.78± 11.97	22.11± 10.30	NS
ALP U/L (Alkaline phosphatase)	Day 0	165.00±61.17	159.30± 61.55	NS
	Day 9	164.40± 45.57	166.40± 68.15	NS
	Day 60	181.10± 54.93	183.70± 81.98	NS
Bilirubin Total mg/dl	Day 0	0.82± 0.37	0.67± 0.30	NS
	Day 9	0.77± 0.35	0.58± 0.34	P<0.0256
	Day 60	0.75± 0.38	0.58± 0.31	P<0.0397
Serum Creatinine mg/dl	Day 0	0.80± 0.09	0.78± 0.08	NS
	Day 9	0.82± 0.07	0.84± 0.11	NS
	Day 60	0.85± 0.09	0.84± 0.10	NS
Serum Urea mg/dl	Day 0	34.00 ± 6.34	31.21 ± 7.32	NS
	Day 9	36.11 ± 8.42	31.56 ± 6.77	P<0.0152
	Day 60	34.81 ± 6.46	32.13± 7.51	NS
Serum Lipid mg/dl	Day 0	570.70± 130.90	532.10± 101.80	NS
	Day 9	551.90 ±119.10	522.80 ±105.50	NS
	Day 60	587.50 ± 120.20	577.70 ±122.00	NS
Serum Total Cholesterol mg/dl	Day 0	172.70 ± 36.79	168.00 ± 36.74	NS
	Day 9	164.30 ± 34.21	159.60 ± 35.51	NS
	Day 60	185.10 ± 35.19	179.50 ± 41.12	NS
HDL Cholesterol mg/dl	Day 0	66.67± 3.94	68.83 ± 4.72	NS
	Day 9	68.94 ± 4.41	68.21 ± 4.07	NS
	Day 60	67.50± 7.54	68.95± 4.76	NS
LDL Cholesterol mg/dl	Day 0	87.60 ± 33.68	86.31 ± 35.90	NS
	Day 9	79.77 ± 28.39	76.71 ± 34.41	NS
	Day 60	100.70 ± 31.17	94.63 ± 41.42	NS
Serum Triglyceride mg/dl	Day 0	92.02 ± 68.92	64.1±32.55	P<0.0337
	Day 9	86.93 ± 66.73	73.68 ± 44.05	NS
	Day 60	80.87 ± 55.82	82.42 ± 49.06	NS

Statistical Analysis: Unpaired t-test for between the group analysis using two tailed p value.

FIGURES

Figure 1

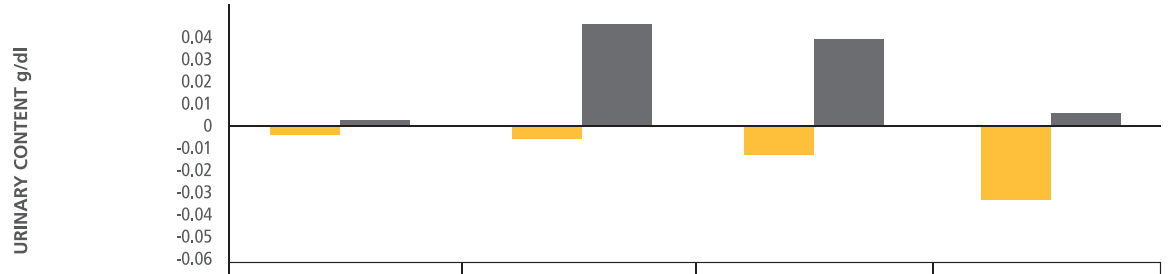
TOTAL NITROGEN CONTENT - Fecal g%



	Day 9	Day 18	Day 28	Day 60
LivNitro+	-0.11	-0.06	-0.08	-0.08
Placebo	0.01	0.05	0.05	0.06

Figure 2

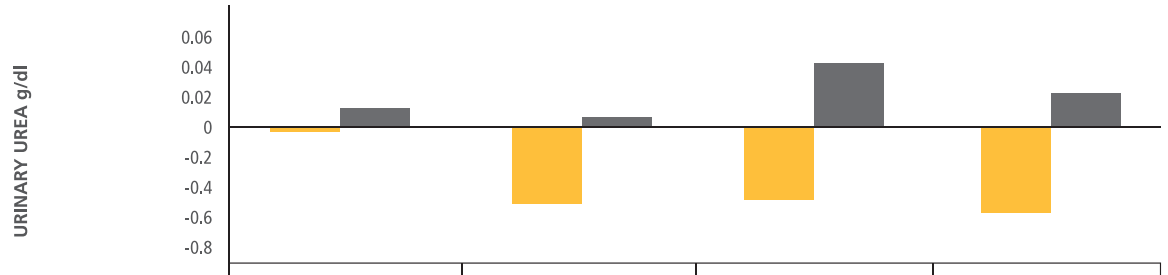
TOTAL NITROGEN CONTENT - Urinary g/dl



	Day 9	Day 18	Day 28	Day 60
LivNitro+	-0.01	-0.47	-0.13	-0.32
Placebo	0.03	0.05	0.29	0.06

Figure 3

TOTAL NITROGEN CONTENT - Urinary Area



	Day 9	Day 18	Day 28	Day 60
LivNitro+	-0.02	-0.47	-0.44	-0.57
Placebo	0.14	0.04	0.41	0.22

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