Alleviation of insulin resistance and liver damage by oral administration of Imm124-E is mediated by increased Tregs and associated with increased serum GLP-1 and adiponectin. Results of a Phase I/II clinical trial.

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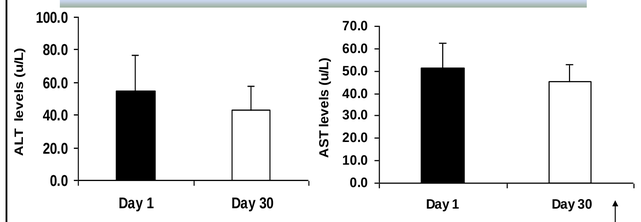
INTRODUCTION

- Metabolic syndrome is a chronic inflammatory disorder associated with insulin resistance and hepatic steatosis.
- Anti LPS colostrum (Imm124-E) is a bovine colostrum raised against LPS from an E.coli extract.
- Imm124-E was shown to exert an immunomodulatory effect and to alleviate target organ damage in animal models.
- Aim: To determine the safety and efficacy of oral administration of anti LPS colostrum to patients with insulin resistance and NASH.

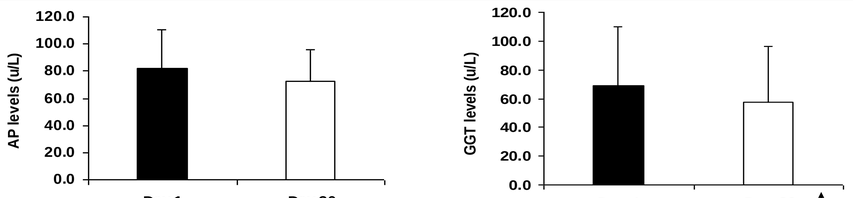
METHODS

- In an open-label trial, 10 subjects with biopsy proven NASH and insulin resistance or diabetes type II were orally treated for 30 days with Imm124-E (600 mg a day).
- Subjects were monitored for serum levels of insulin, adiponectin, and GLP-1 and for the changes of expression in peripheral regulatory T cells (Tregs).
- Clinical effect was evaluated by: OGTT, liver enzyme, and lipid profile. The comparison was done between day 1 and day 30 for each patient.
- Data analysis was carried out on responders.

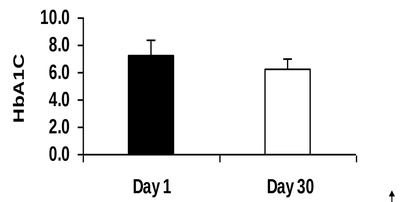
RESULTS



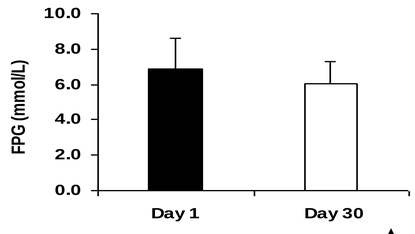
Administration of Imm124-E improved hepatocellular liver enzymes levels p<0.04.



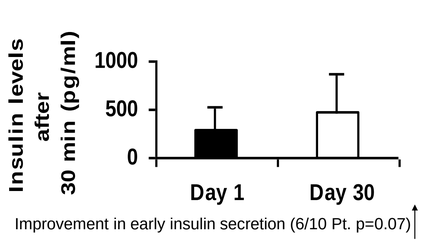
Administration of Imm122-E improved cholestatic liver enzymes levels (7/10 Pt. p<0.002)



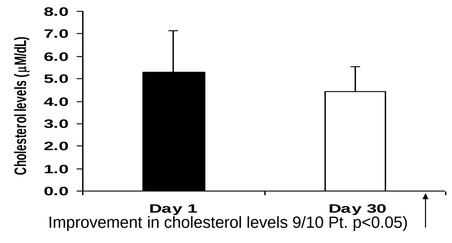
Improvement in HBA1C levels (9/10 Pt. p<0.001)



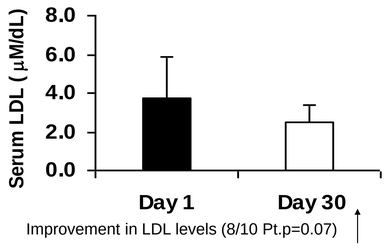
Improvement in FGT levels (6/10 Pt. p<0.06)



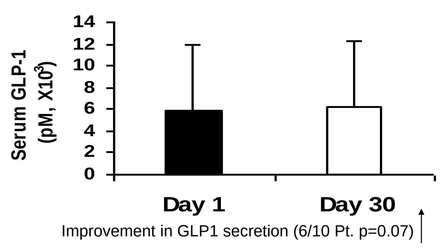
Improvement in early insulin secretion (6/10 Pt. p=0.07)



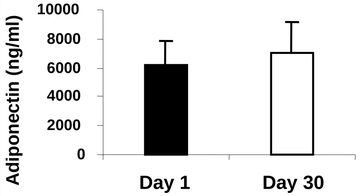
Improvement in cholesterol levels 9/10 Pt. p<0.05)



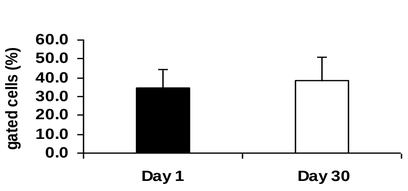
Improvement in LDL levels (8/10 Pt.p=0.07)



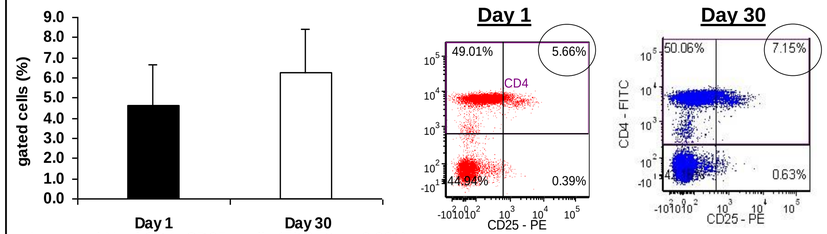
Improvement in GLP1 secretion (6/10 Pt. p=0.07)



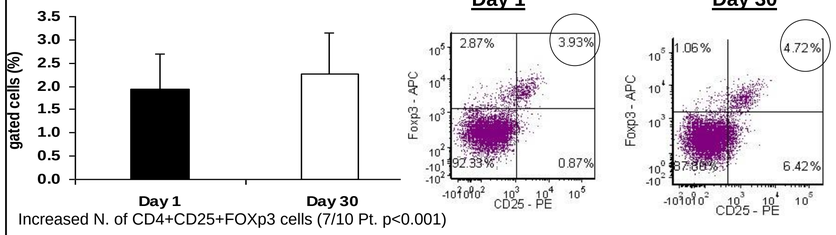
Increased Adiponestin secretion (8/10 Pt.p=0.08)



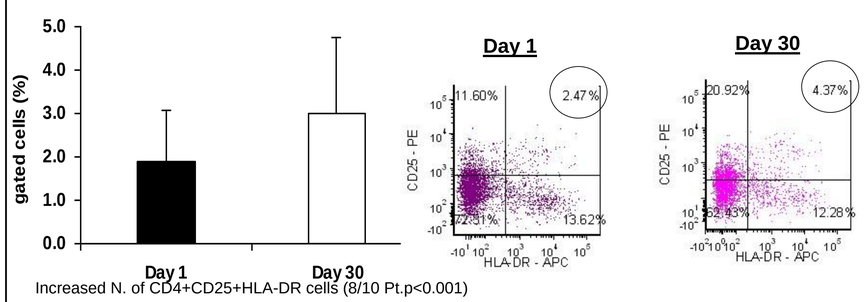
Increased N. of CD4+CD62+ cells (6/10 Pt. p<0.002)



Increased N. of CD4+CD25+ cells (7/10 Pt. p<0.001)



Increased N. of CD4+CD25+FOXp3 cells (7/10 Pt. p<0.001)



Increased N. of CD4+CD25+HLA-DR cells (8/10 Pt.p<0.001)

CONCLUSION

- Oral administration of Imm124-E exerts an immunomodulatory effect in subjects with insulin resistance or type 2 diabetes, hyperlipidemia and NASH.
- The anti-inflammatory effect and promotion of peripheral Tregs, were in some of the responders associated with alleviation of insulin resistance and NASH in these subjects.

DISCLOSURE

* Medical Director of Immuron.
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