

Antioxidant and immunomodulatory effects of Viusid® in patients with chronic hepatitis C: a double-blind and placebo-controlled study.

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Background

- Peginterferon plus ribavirin is the only therapeutic alternative for chronic hepatitis C (CHC).
- Unfortunately, sustained virological response is achieved in only approximately 50% of the patients.
- The pathogenesis of chronic hepatitis C (CHC) is associated with severe oxidative stress and non-selective immunological disturbance that lead to necroinflammation and the progression of fibrosis.
- Viusid, an antioxidant and immunomodulatory cocktail, improves histological and biochemical parameters such as steatosis, inflammation, fibrosis, and aminotransferase in patients with CHC and NAFLD.
- A randomized double-blind and placebo-controlled study was conducted to evaluate whether Viusid may have a beneficial effect on oxidative stress and cytokine parameters in patients with chronic hepatitis C.

Ingredients of Viusid

Malic acid	0.666g	Glycyrrhizic acid	0.033g
Arginine	0.666g	Glucosamine	0.666g
Glycine	0.333g	Calcium pantothenate	0.002g
Folic acid	66 mcg	Ascorbic acid	0.020g
Pyridoxal	0.6 mg	Cyanocobalamine	0.3 mcg
		Zinc sulfate	0.005 g

Methods

Patients "Sixty patients with CHC were recruited at a tertiary care center (National Institute of Gastroenterology, Havana, Cuba)"

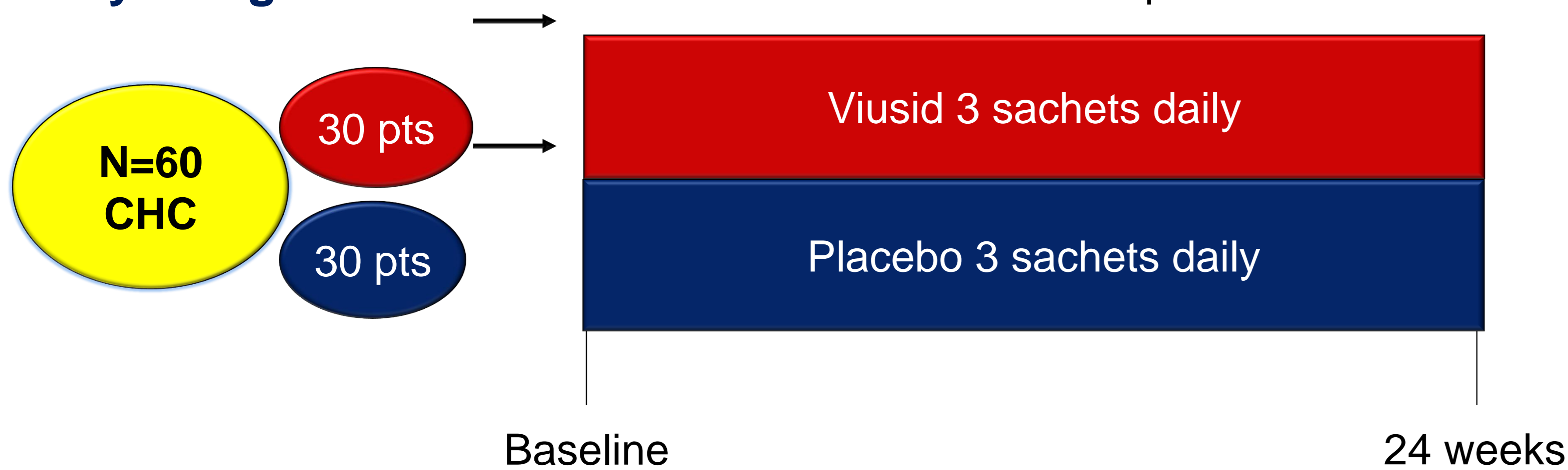
Inclusion criteria

- Male and female patients of 18 to 65 years of age
- A positive test for anti-HCV antibody and HCV RNA detectable in serum by PCR
- Persistently elevated ALT at least on two occasions
- Liver biopsy consistent with chronic hepatitis
- Non responders to previous treatment with peginterferon plus ribavirin
- Absence of significant alcohol ingestion (weekly ethanol consumption of less than 40 g)

Exclusion criteria

- Presence of any other form of liver disease
- Positive screening for viral hepatitis A and B and HIV
- Pregnancy or lactation
- Decompensated cirrhosis
- Concomitant disease with reduced life expectancy
- Severe psychiatric conditions

Study design "A double-blind and randomized-controlled phase II clinical trial"



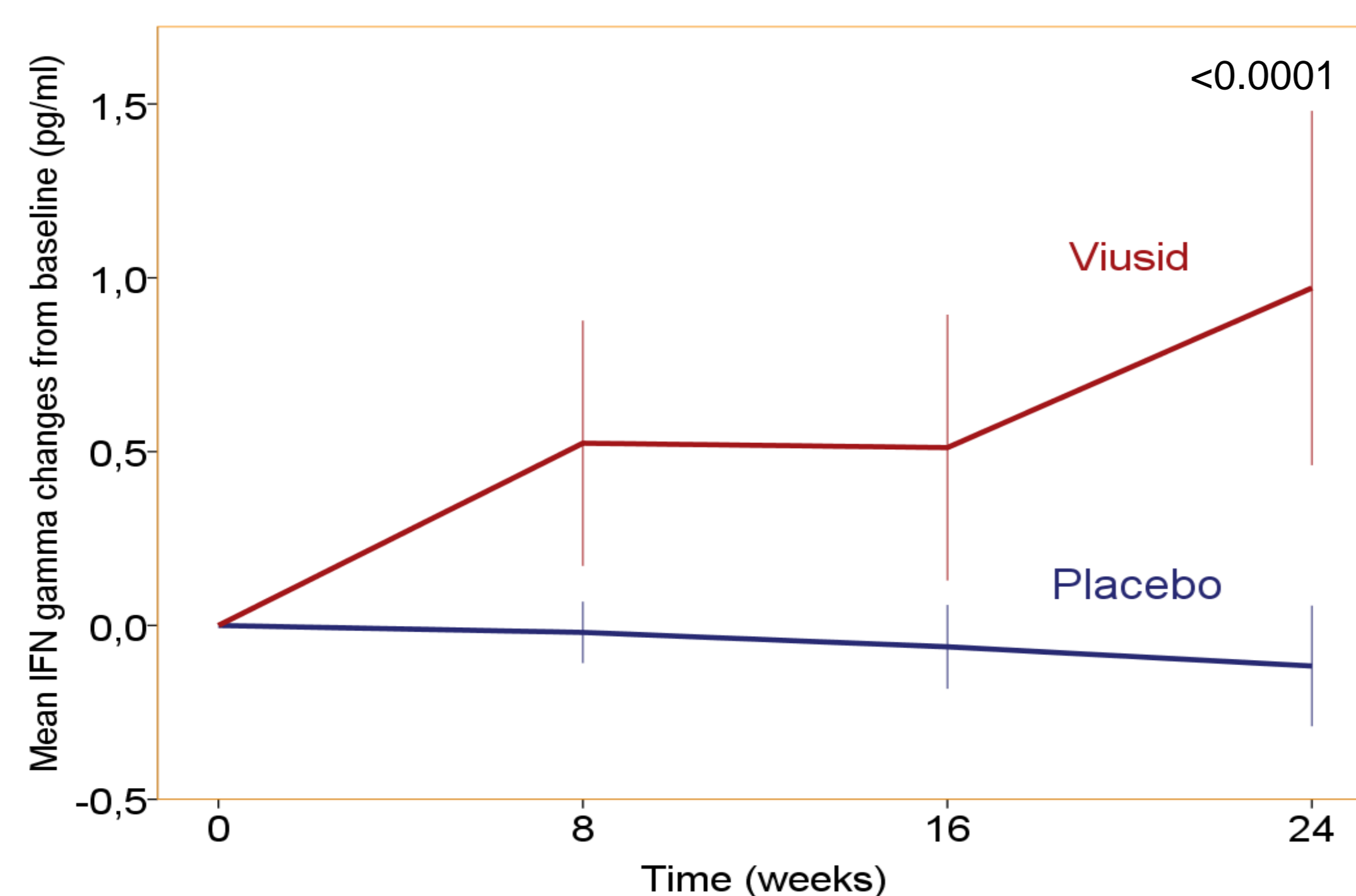
Outcomes measures

- **Primary outcome:** Changes in serum malondialdehyde (MDA) (lipid peroxidation products)
- **Secondary outcome:** Changes in serum TNF- α , IL-10 and IFN- γ

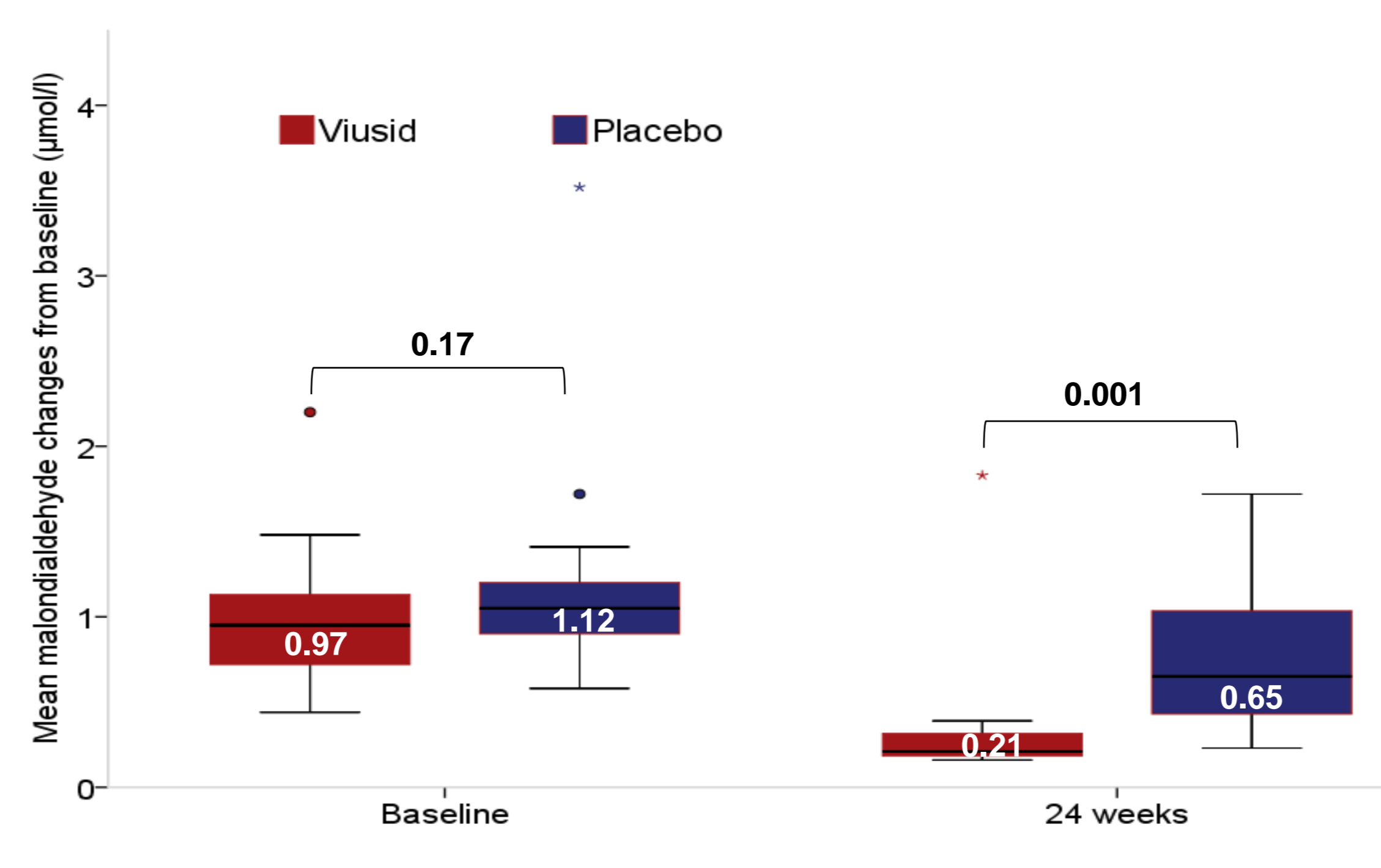
Change was the difference between measurements obtained at baseline and at the end of treatment (24 weeks).

Results

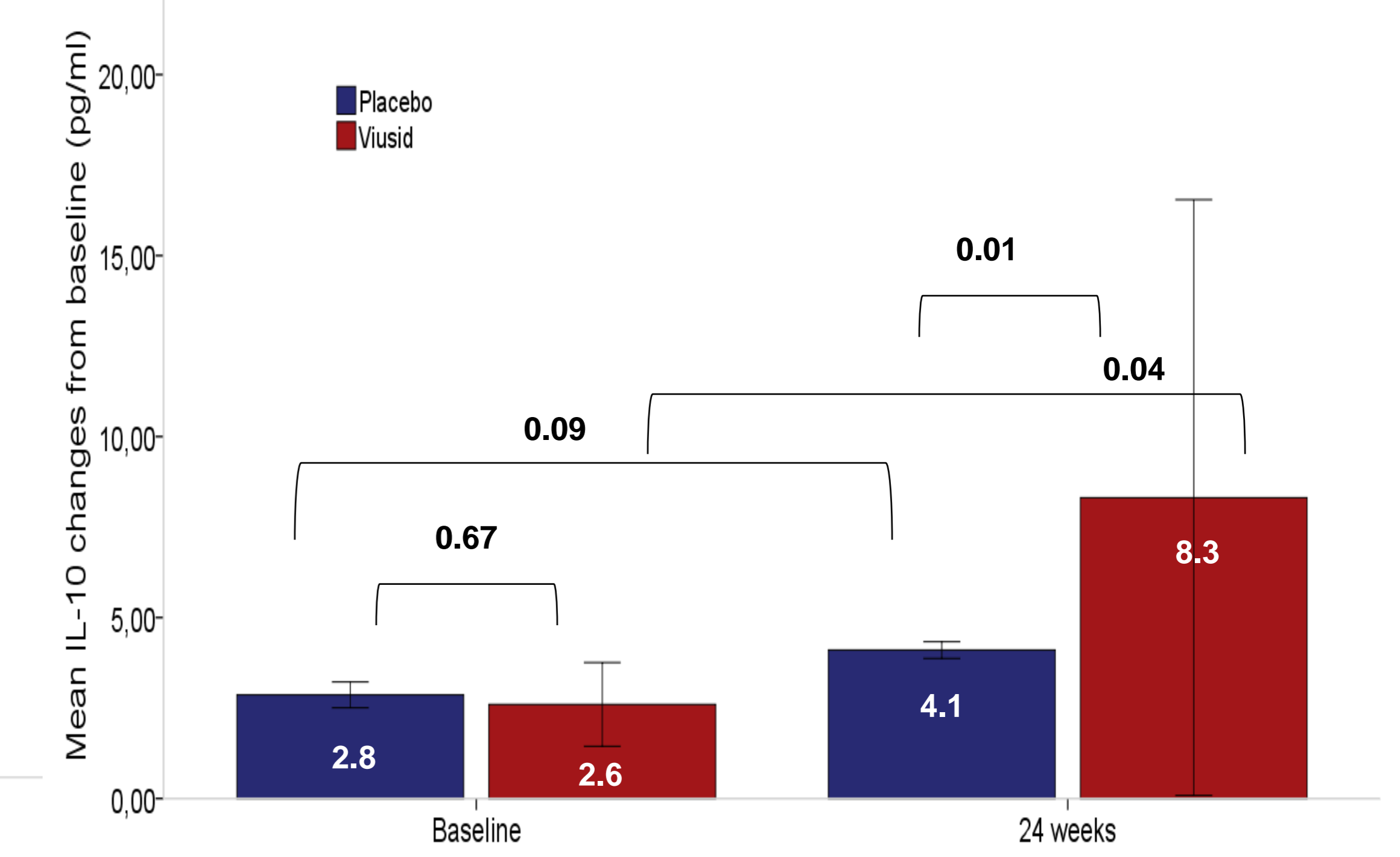
Mean changes from baseline in serum IFN- γ



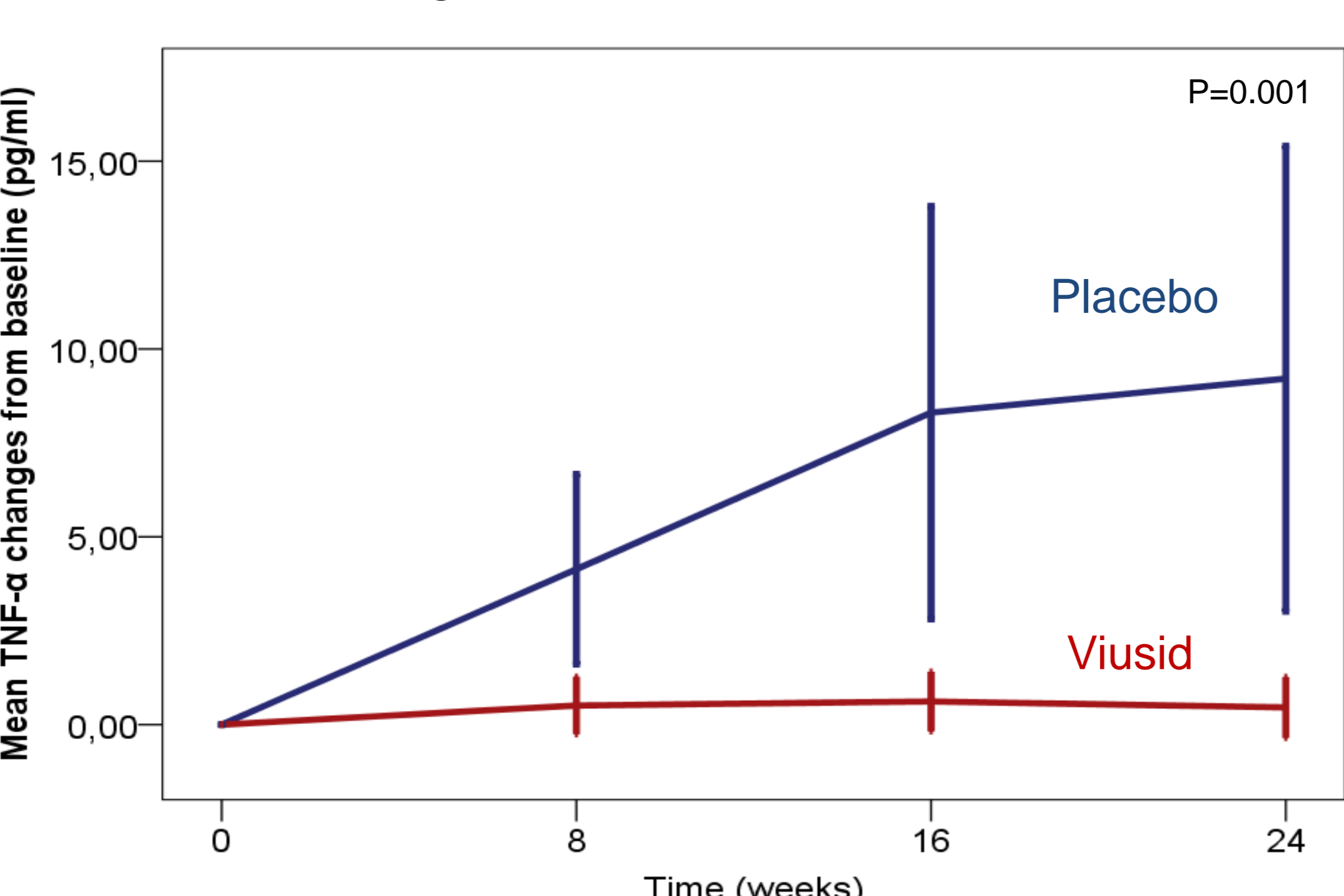
Mean changes from baseline in serum MDA



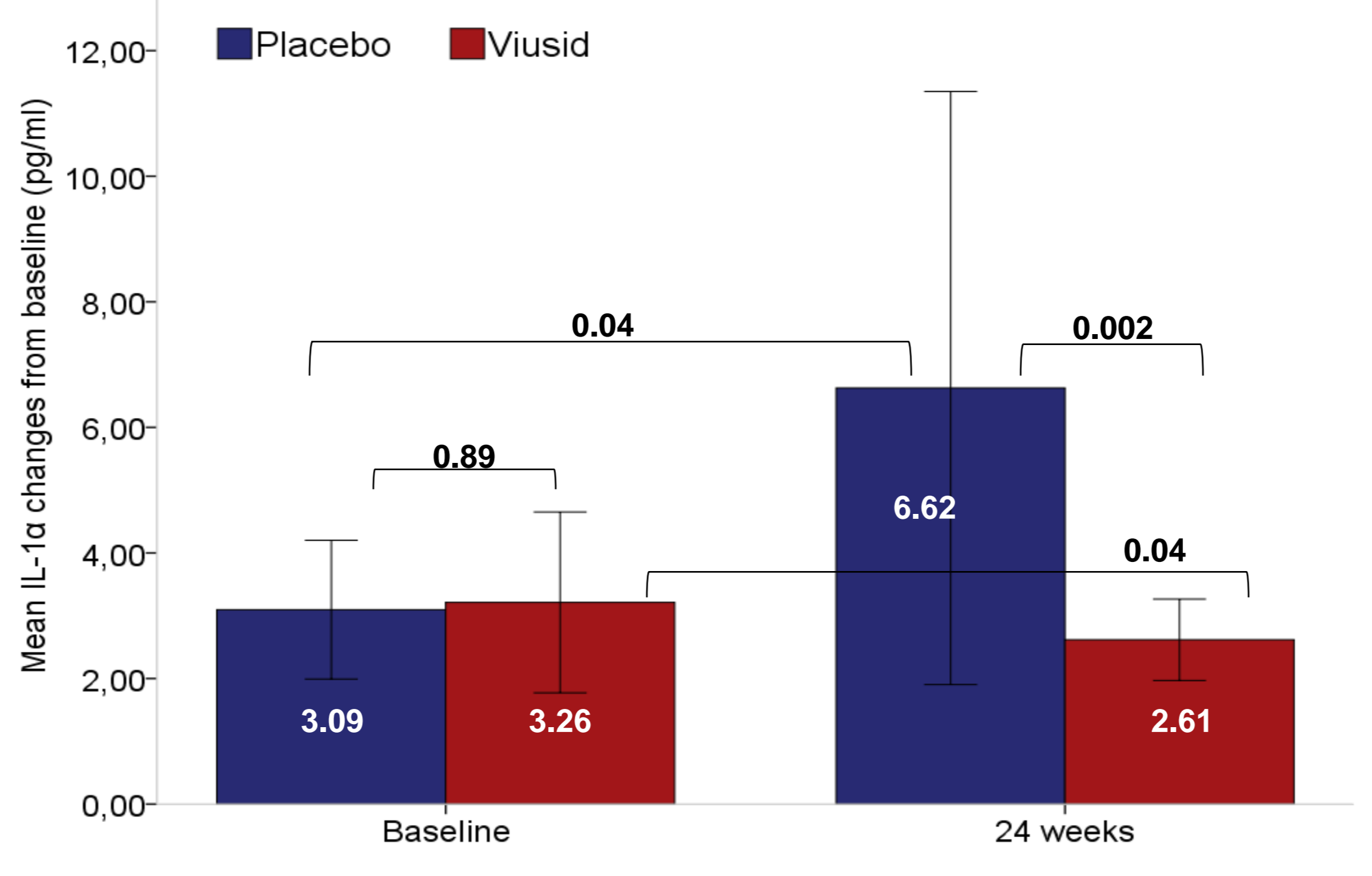
Mean changes from baseline in serum IL-10



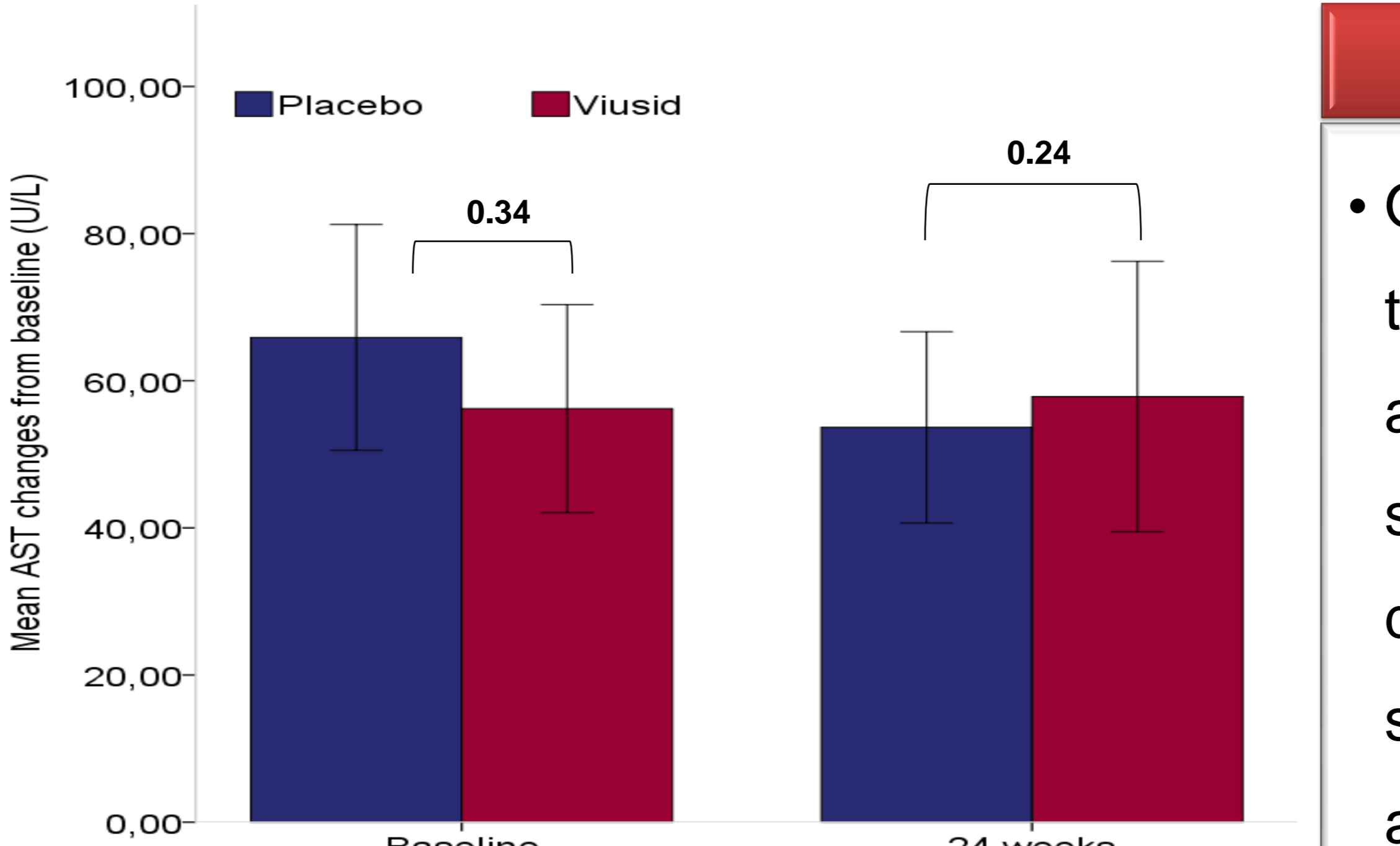
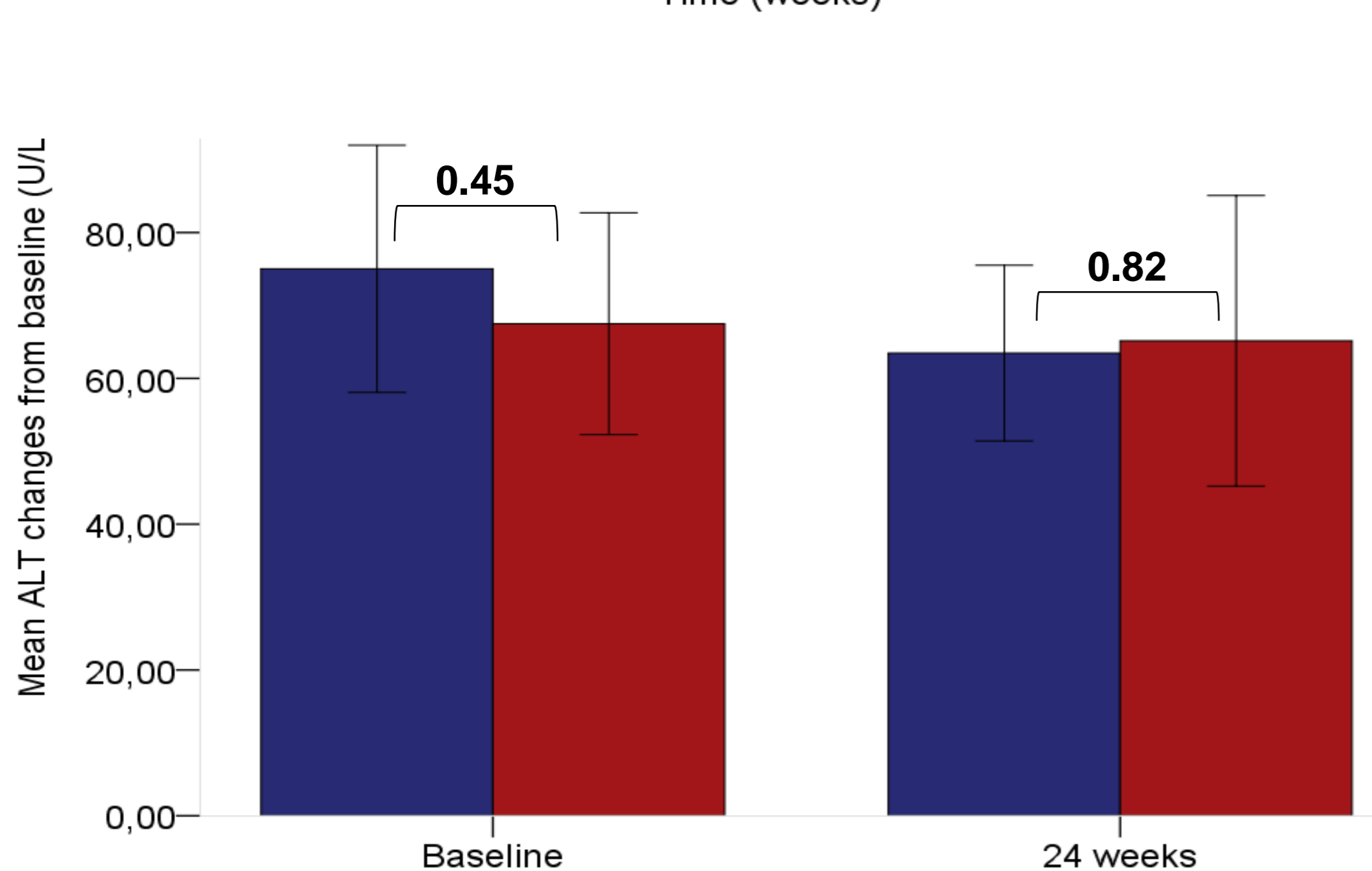
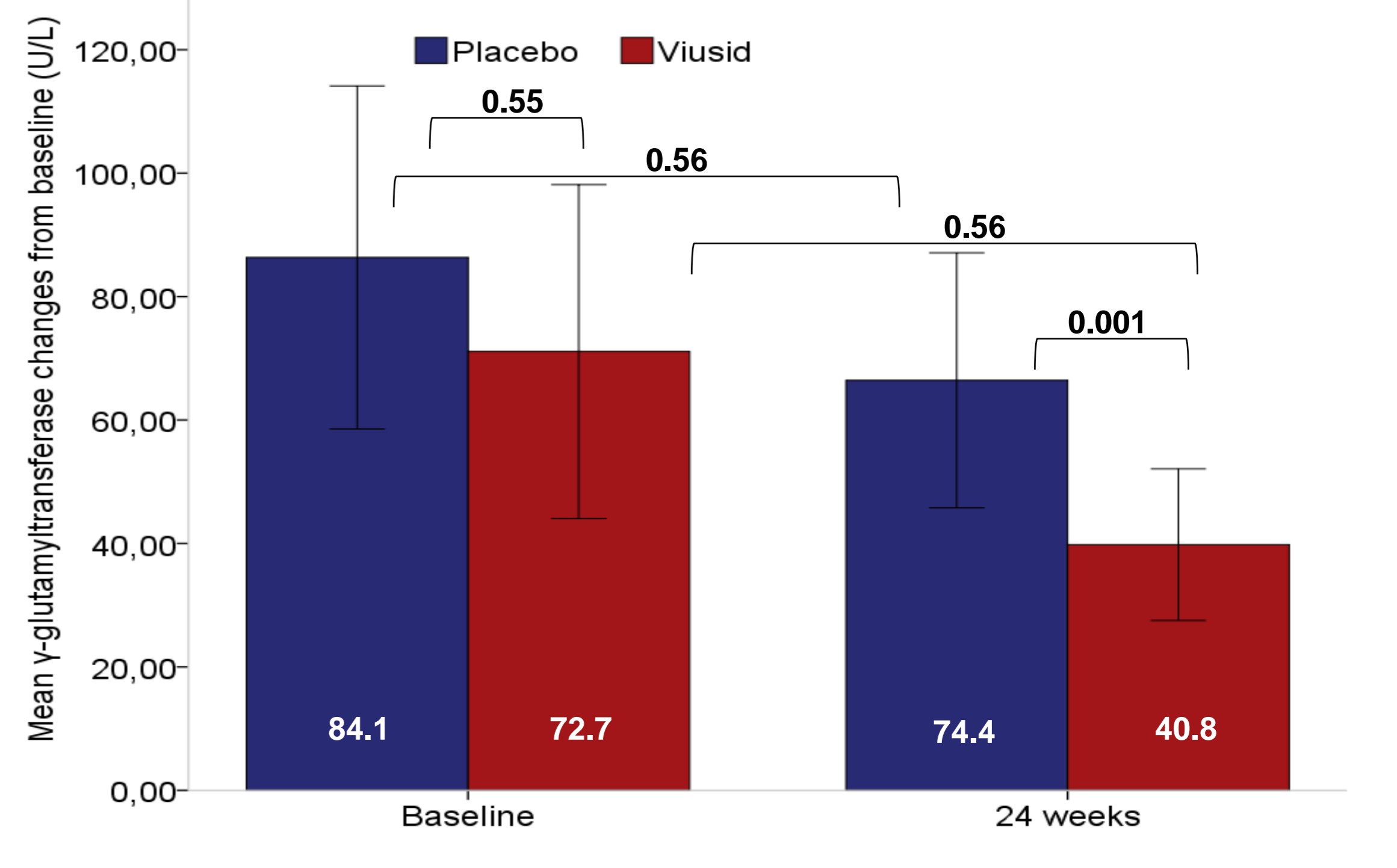
Mean changes from baseline in serum TNF- α



Mean changes from baseline in serum IL-1 α



Mean changes from baseline in serum GGT



Conclusions

- Our data suggest that Viusid improves oxidative stress through reduction of lipid peroxidation products (MDA) and has an immunomodulatory effect on cytokine secretion via increased production of IFN- γ and IL-10, decreased production of IL-1 α , and stabilized TNF- α secretion in patients with CHC who have failed previous antiviral treatment.

Error bars indicate SEM
Comparative analysis was performed using Wilcoxon Sum Rank Test

Disclosure: The study was supported in part by a grant from Catalysis Laboratories, Spain. They provided the Viusid sachets and the reagent kits for oxidative stress and cytokine determinations.