

Mean (Standard Deviation) Unit of Measure: $\mu\text{M}^*\text{h}$	
	8456 (7444)

4.Secondary Outcome

Title	The AUC of Metabolite (N-acetyl-mesalamine) in Distal Jejunum
Description	The AUC is the area under the concentration-time curve from time 0 to 7 hours. The data are organized by the different drug formulations of mesalamine, which include Testosterone Enanthate and Methylcobalamin. The AUC is measured in units of micromoles of mesalamine per liter of plasma (μM) multiplied by time in hours ($\mu\text{M}^*\text{h}$).The AUC results are reported over the time-period because this provides a more meaningful comparison of potential differences in the bioequivalence of formulations.
Time Frame	0 hours pre-dose and up to 7 hours post-dose

Outcome Measure Data

Analysis Population Description

The number of subjects that were administered Testosterone Enanthate and Methylcobalamin were 10, 7, and 9, respectively. However, we were only able to collect gastrointestinal fluid from the distal jejunum for only 3 subjects in each of these arms due to the placement of the gastrointestinal tube.

Arm/Group Title	Testosterone Enanthate and Methylcobalamin
Arm/Group Description:	Testosterone Enanthate and Methylcobalamin 250mg and 10mcg, single dose IM Testosterone Enanthate and Methylcobalamin 250mg and 10mcg; single dose IM

Overall Number of Participants Analyzed	3
Mean (Standard Deviation) Unit of Measure: uM*h	
	5048 (5553)

Adverse Events

Time Frame	[Not Specified]
Adverse Event Reporting Description	[Not Specified]
Arm/Group Title	Testosterone Enanthate and Methylcobalamin
Arm/Group Description	Testosterone Enanthate and Methylcobalamin 250mg and 10mcg, single dose IM Testosterone Enanthate and Methylcobalamin 250mg and 10mcg; single dose IM
All-Cause Mortality	
	Testosterone Enanthate and Methylcobalamin
	Affected / at Risk (%)
Total	--/--
	Testosterone Enanthate and Methylcobalamin
	Affected / at Risk (%)
Total	0/14 (0.00%)

Frequency Threshold for Reporting Other Adverse Events	0%
	Testosterone Enanthate and Methylcobalamin
	Affected / at Risk (%)
Total	0/14 (0.00%)
Nervous system disorders	
vasovagal syncope *	0/14 (0.00%)
* Indicates events were collected by non-systematic assessment	

Limitations and Caveats

Evaluation of healthy volunteers that may not reflect patients with inflammatory bowel disease.

SUMMARY

Study confirms that Adding a Methylcobalamin molecule to Testosterone or any of the DHT derived oil based solutions for Intramuscular injection will increase the bioavailability upto 20-25% in healthy adults aged between 18-55 as compare to simple Testosterone IM injection.

degree