

IMMUNOLOGICAL EFFECTS OF SYNBIOTIC SUPPLEMENTATION IN ADVANCED HIV DISEASE

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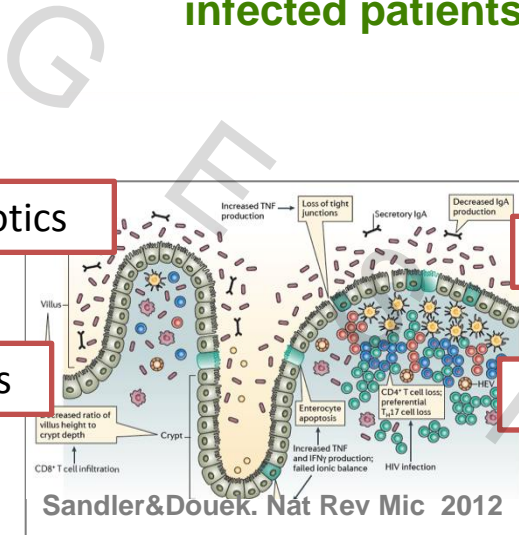
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INTRODUCTION

- HIV-infected patients diagnosed late show poorer immunological recovery and increased morbidity and mortality .
- Nutritional interventions targeting the MALT in naïve patients have demonstrated to slow down the CD4+ T cell decline and to reduce levels of bacterial translocation.
- Our objective is to evaluate whether an immunomodulatory nutritional intervention in late presenters HIV-infected patients can improve the immunological recovery achieved after the initiation of antiretroviral therapy.

PROMALTIA STUDY

Effects of an immunomodulatory nutritional intervention on the immune recovery of HIV-infected patients late-presenters. FIS PI13/00438



Pre/Probiotics

EPA, DHA, GLA

Oligonutrients

Essential aminoacids

Sandler&Douek. Nat Rev Mic 2012

76 randomized
5 did not initiate the study
2 withdrew informed CI
4 deaths before w24
2 did not show up at w24

Inclusion criteria:

AIDS or CD4<350, ART naive

Primary Outcome:

CD4 increase

Secondary outcomes:

CD4/CD8

Safety

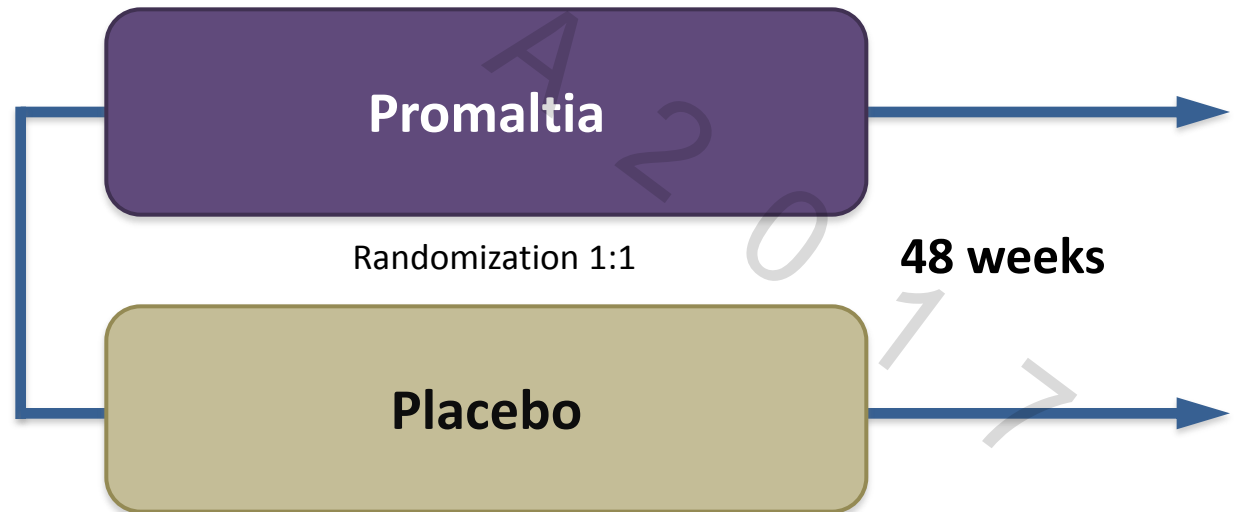
Inflammatory and bacterial

translocation biomarkers

T cell activation

Microbiota composition

and function



Promaltia

Randomization 1:1

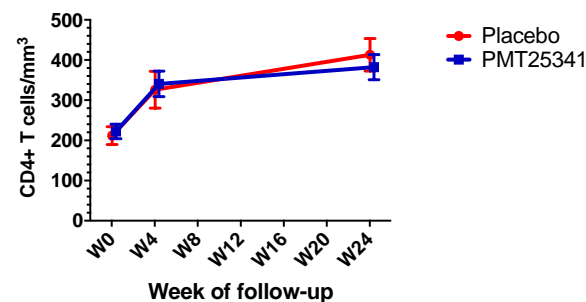
48 weeks

Placebo

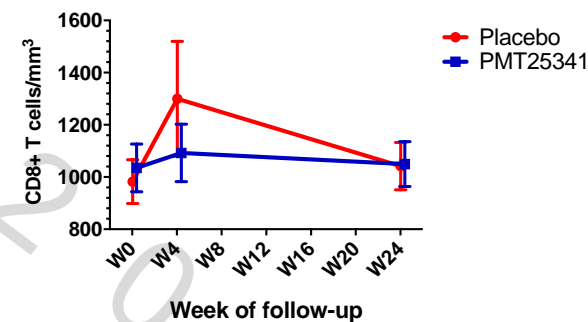
RESULTS

General characteristics	PMT25341 N=37	Placebo N=27	Total N=64
Age, years (mean±SD)	35±10	39±15	37±12
Women (N, %)	5 (17%)	2 (8%)	
CD4, cells/uL (mean±SD)	224±110	211±114	219±111
CD4/CD8 ratio (mean±SD)	0.28±0.21	0.26±0.18	0.26±0.19
Baseline HIV RNA cop/ml (mean±SD)	94478±107282	30678±14487	79820±107282
AIDS Defining conditions (N, %)	4 (11%)	2 (7%)	6 (9%)
Risk category (N, %)			
Men who have sex with men	27 (73%)	24 (89%)	51 (80%)
Heterosexual	9 (24%)	2 (7%)	11 (17%)
Injection Drug Users	1 (3%)	1 (4%)	2 (3%)
First-line ART			
INSTI-based	20 (54%)	17 (63%)	37 (58%)
NNRTI-based	11 (30%)	6 (22%)	17 (27%)
PI-based	6 (16%)	4 (15%)	10 (15%)

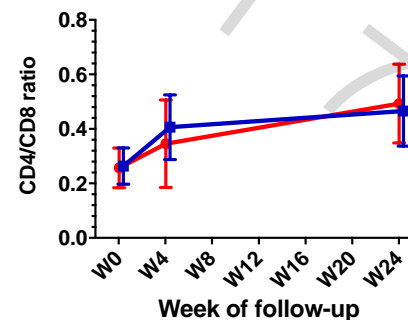
Effects of PMT25341 on CD4+ T cell counts



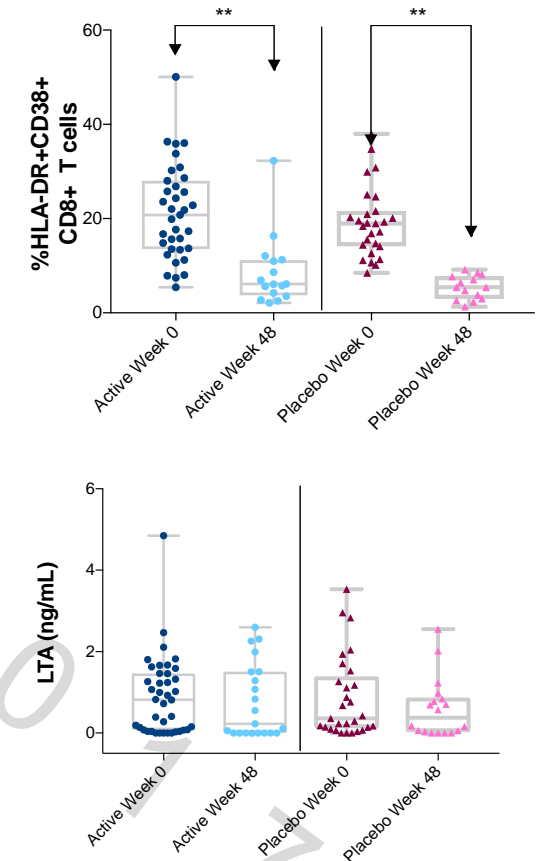
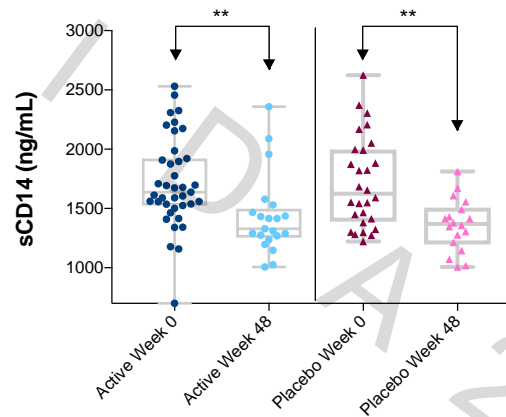
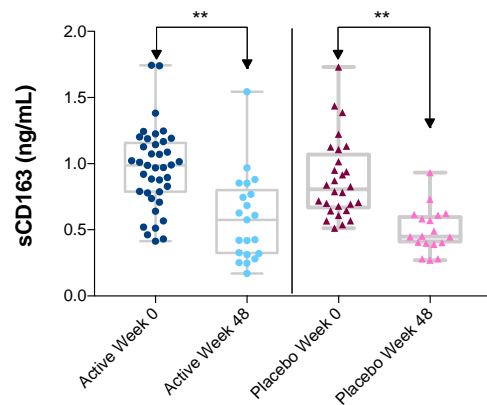
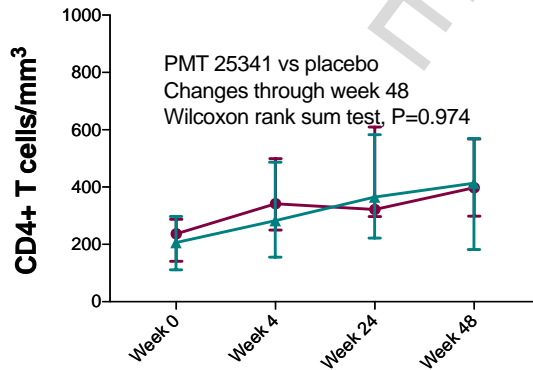
Effects of PMT25341 on CD8+ T cell counts



Effects of PMT25341 on CD4/CD8 ratio



RESULTS



CONCLUSIONS

While a positive effect on CD4 T counts has been observed in previous studies evaluating the impact of prebiotics and probiotics in ART-naive subjects, our data suggest that the clinical impact of nutritional strategies aimed at restoring the gut microbiota might be very limited in HIV-infected patients initiating ART at advanced disease.

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