

The Benefit of Montelukast in Atopic Dermatitis Induced by Food Allergies



303.773.9000 | 877.8IMMUNE
 www.IMMUNOe.com | info@IMMUNOe.com

INTRODUCTION

- Atopic Dermatitis (AD) exhibits a mixture of immunological and pharmacological abnormalities
- Commencement of the immune cascade can result from multiple activators including allergens — food or environment — infections or stress
- Cysteinyl leukotrienes (Cys-LTs) are potent mediators of allergic inflammation
- In our previous work, we have shown the role of nerve growth factor (NGF) in the pathogenesis of AD
- Cys-LTs levels are elevated in patients with AD
- Cys-LTs are involved in eosinophilic infiltration of the GI tract

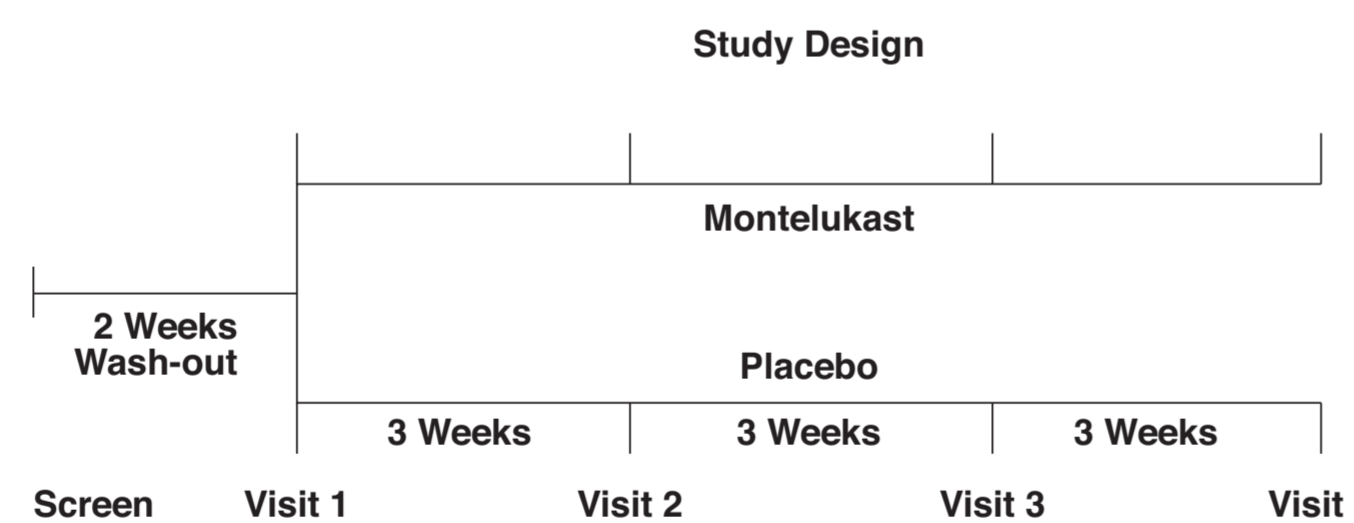
HYPOTHESIS

- Montelukast may down-regulate the inflammatory processes caused by food triggers
- Montelukast may down-regulate NGF production
- Montelukast may down-regulate pro-inflammatory pathways, possibly via NGF and thus regulate allergy related syndromes such as AD and eosinophilic gastroenteritis.

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 IRB approved: Quorum Review IRB# 23389/1
 ClinicalTrials.gov Identifier: NCT00557284

METHODS

- Randomized, double-blind placebo controlled
- Inclusion criteria
 - 1 – 8 years old
 - Evidence of food allergy
 - Evidence of AD (10 – 25% body coverage)
 - Evidence of GI symptoms

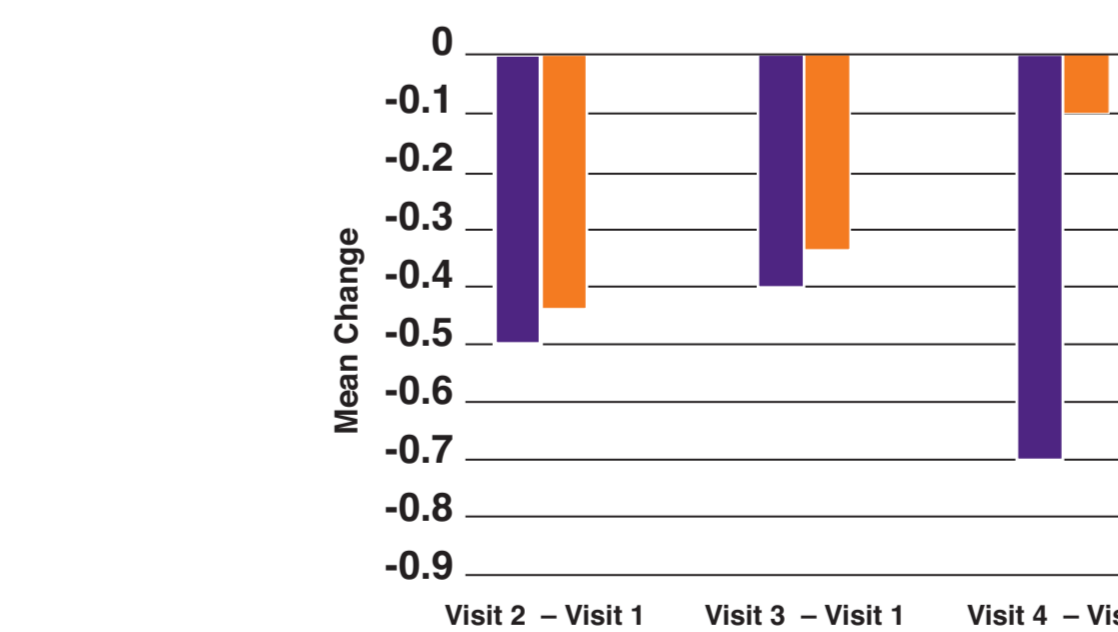
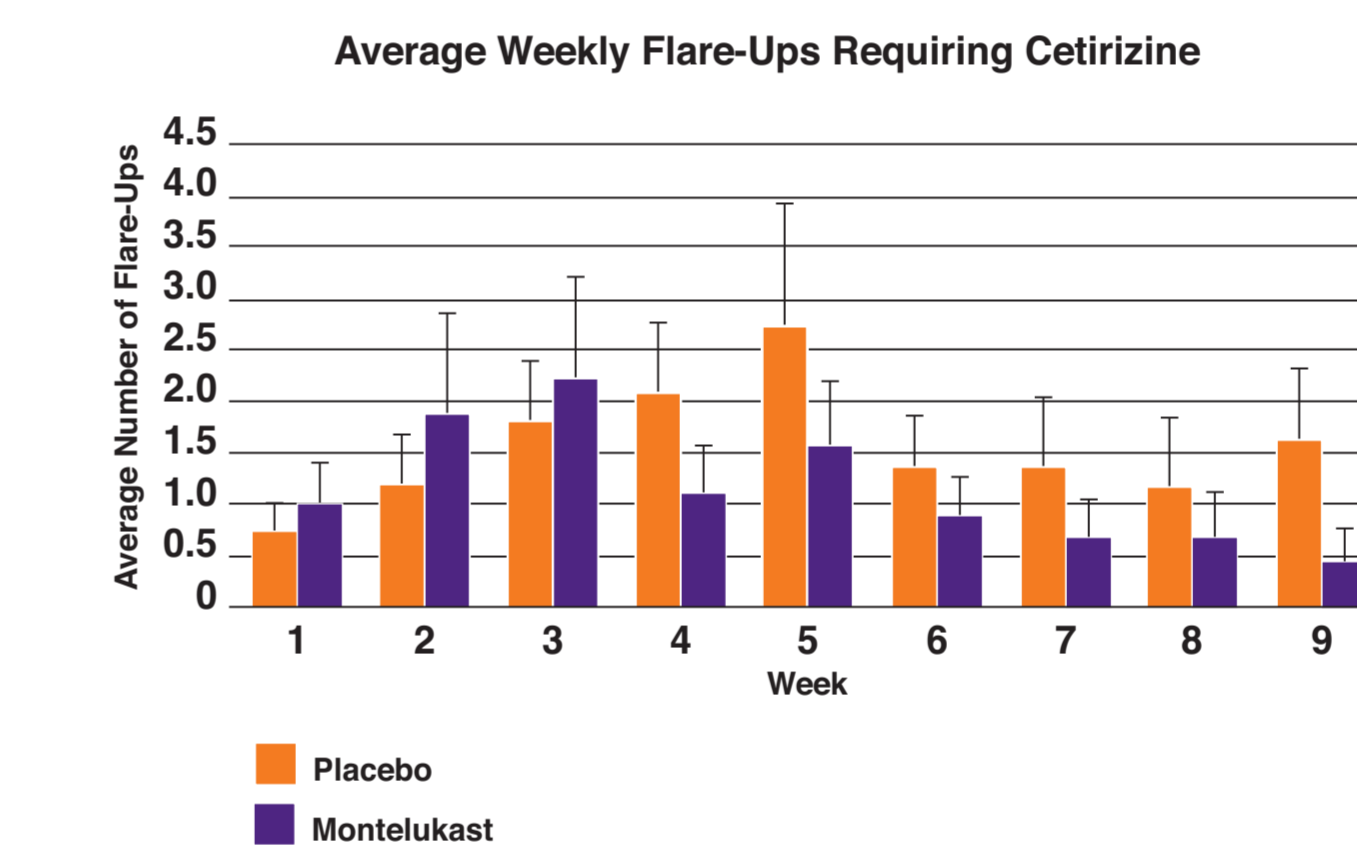
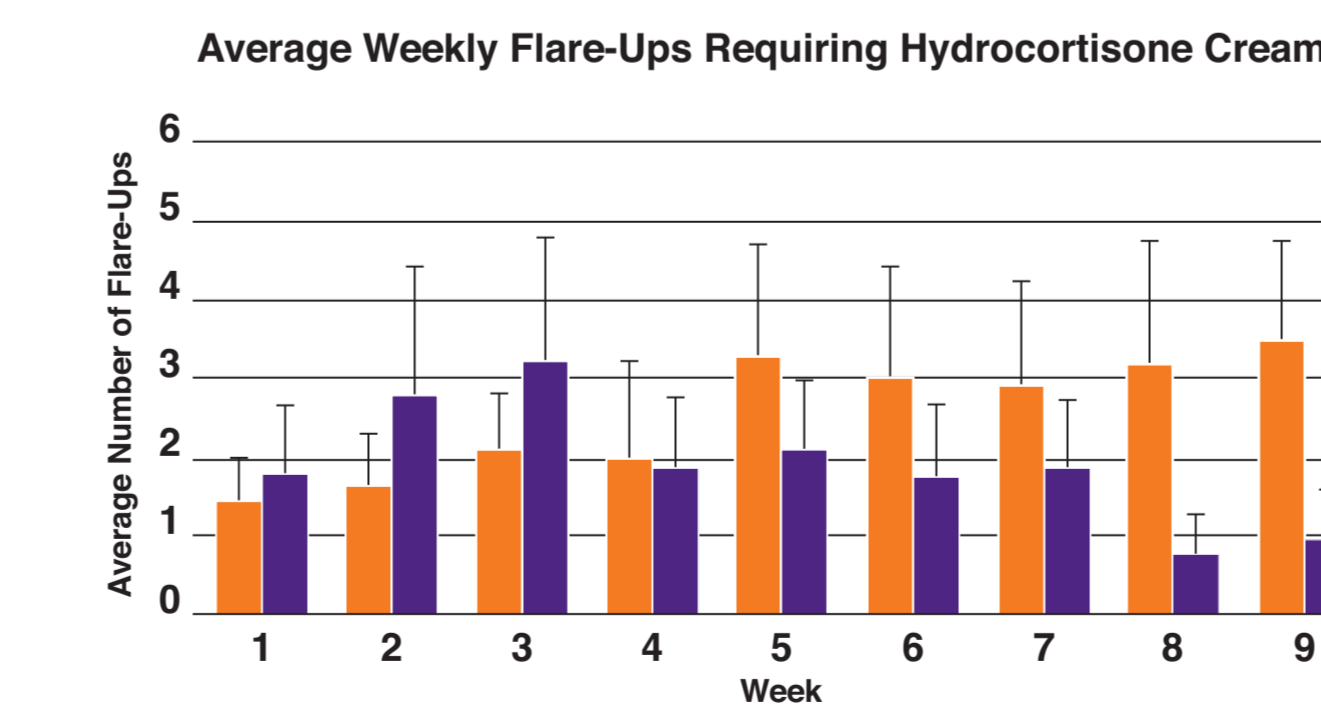
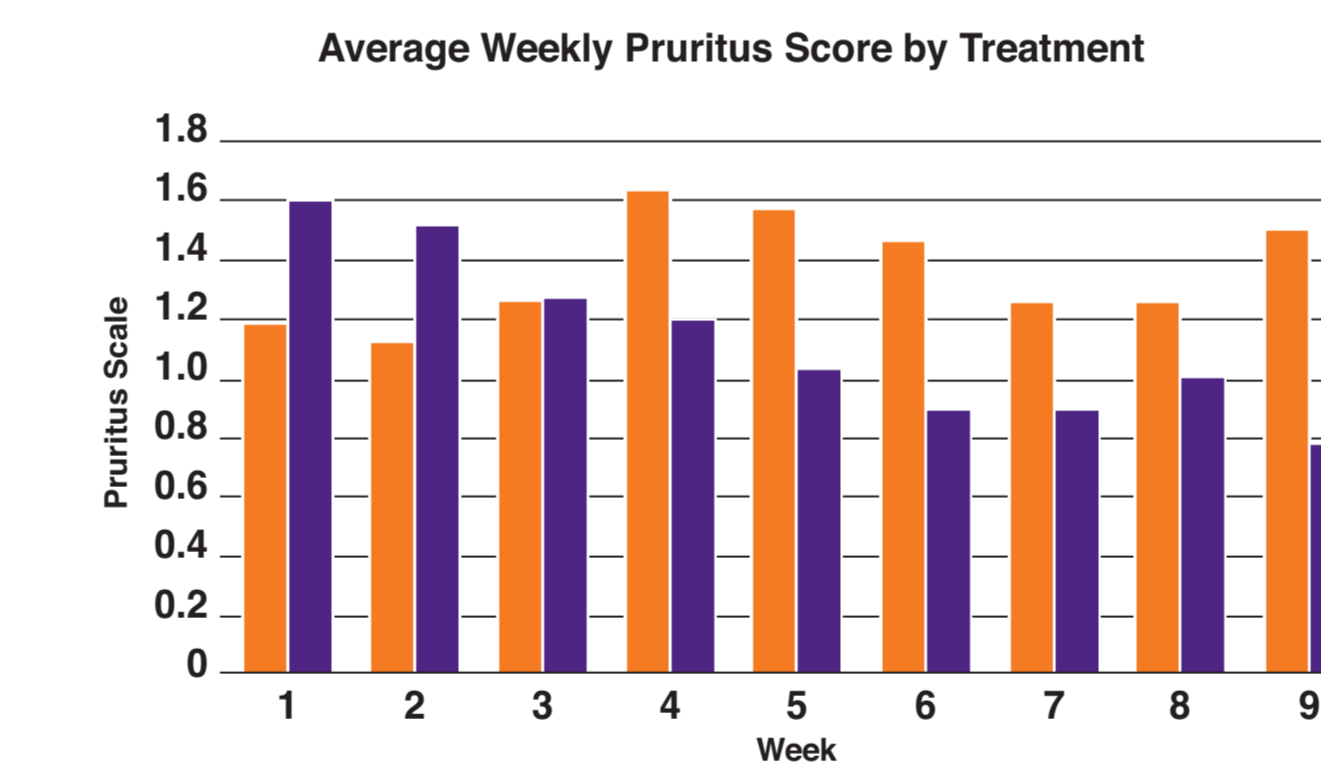


- Subjects were given:
 - liquid cetirizine and 1% hydrocortisone cream for use as needed as rescue medication
 - diary to document rescue medication usage (AD flare-up) and AD (pruritus score) and GI symptoms (GSRS score)
- Validated scores
 - Investigators Global Assessment Scores (IGA) for AD severity
 - GSRS for GI symptoms
- Laboratory assessments
 - Urinary LTE-4 levels
 - Serum — NGF, IL-5, IL-13, TNF-alpha
- Statistical analysis
 - Analyzed using ANOVA methods

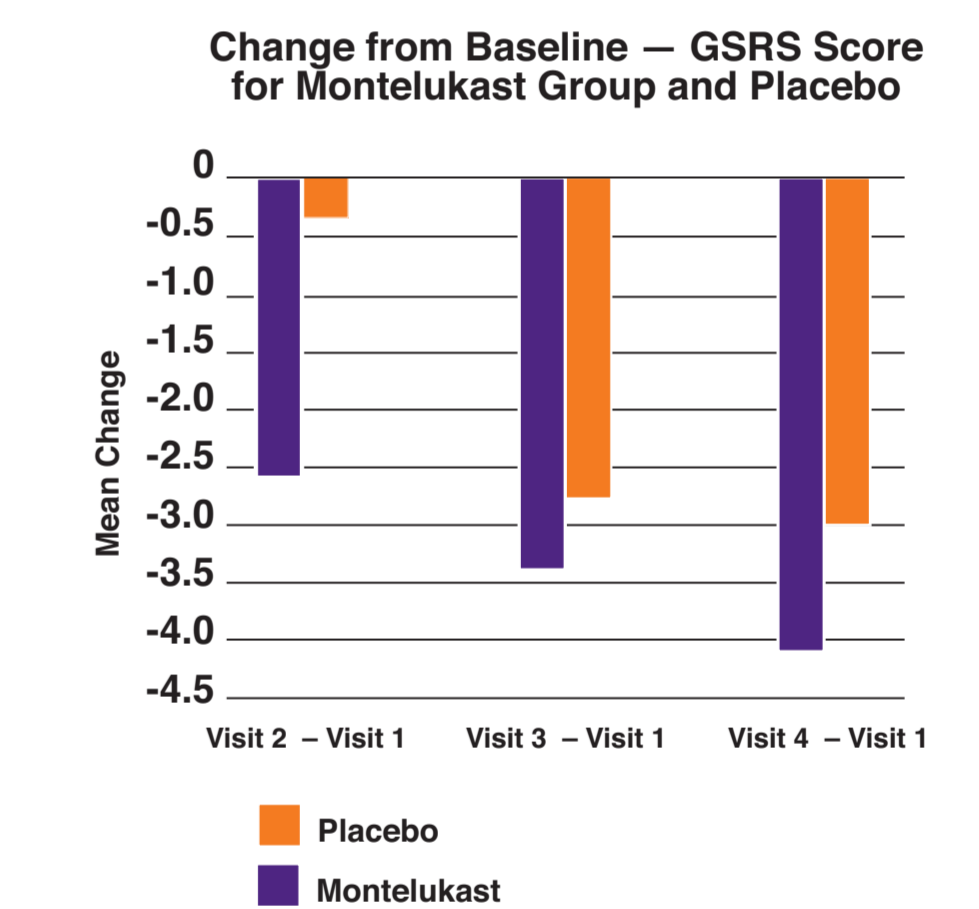
RESULTS

- 33 subjects screened, 20 randomized, mean age of 5.4 years

MONTELUKAST IMPROVED AD SCORES



MONTELUKAST IMPROVED GI SYMPTOMS



MONTELUKAST REGULATES NGF AND TNF ALPHA PRODUCTION

Mean (Std Dev)	Baseline	Comparison	p-value
	Placebo	Treatment	
LN(TNF α)	1.39(.82)	.99(.41)	0.2095
LN(NGF)	3.03(2.4)	2.59(2.6)	0.7005

Log transformed values

CONCLUSION

- Montelukast is involved in inflammatory pathways that may lead to AD and GI symptoms
- NGF may play a role in the pathogenesis of AD
- Montelukast can modify NGF signaling