

Clinical Protocol: A Randomized, Double-Blind, Placebo-Controlled Study of PhytoIntelligence 3.4-Asthma (PI-3.4A) as Adjunctive Therapy in Moderate Bronchial Asthma

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1 Introduction

Asthma is a heterogeneous chronic inflammatory disease characterized by airway hyperresponsiveness (AHR) and structural remodeling. Current standards of care often leave gaps in redox homeostasis and epigenetic regulation. The PI-3.4A formulation is a 6-node botanical stack designed to address these deficiencies.

2 Objectives

2.1 Primary Objective

To evaluate the efficacy of PI-3.4A in improving the Forced Expiratory Volume in 1 second (FEV1) compared to placebo in subjects with stable, persistent asthma.

2.2 Secondary Objectives

1. To assess the reduction in fractional exhaled nitric oxide (FeNO) as a marker of airway inflammation.
2. To quantify the reduction in eosinophil counts in peripheral blood and sputum.
3. To evaluate the safety and tolerability of the 750 mg PI-3.4A capsule twice daily.

3 Formulation Specification (PI-3.4A)

The intervention consists of a single 750 mg organic vegan capsule administered BID.

Node	Component	Role	Mass (mg)
N1	Quercetin Phytosome	D1/D3 (Genomic/Redox)	195
N2	Curcumin Phytosome	D4 (Immune/NF- κ B)	140
N3	Sulforaphane (from 10% BSH)	D3 (Redox/Nrf2)	199
N4	AKBA (Lecithin Form)	D2 (Metabolic/5-LO)	107
N5	6-Shogaol (Ginger Extract)	D5 (Epigenetic/HDAC)	84
N6	Piperine (95% Purity)	D6 (Kinetic Adjuvant)	25
Total			750

Table 1: PI-3.4A Stoichiometric Allocation

4 Inclusion and Exclusion Criteria

4.1 Inclusion

- Age 18–65, non-smokers or stopped >3 months.
- Physician-diagnosed asthma for ≥ 1 year.
- FEV1 between 60% and 80% of predicted values.
- Reversible airway obstruction ($\geq 12\%$ increase in FEV1 post-albuterol).

4.2 Exclusion

- History of severe allergy to ginger, turmeric, or broccoli.
- Concomitant use of CYP3A4 substrates with narrow therapeutic indices (e.g., Warfarin, Digoxin).
- Pregnant or lactating women.

5 Statistical Analysis

Sample size calculation assumes a power of 0.80 and an α of 0.05. Primary endpoint analysis will use an unpaired t -test or ANOVA for change in FEV1 from baseline.