

Efficacy and Safety of Ashwagandha Root Extract in Subclinical Hypothyroid Patients: A Double-Blind, Randomized Placebo-Controlled Trial.

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Abstract

BACKGROUND: Subclinical hypothyroidism, a thyroid disorder without obvious symptoms of thyroid deficiency, occurs in 3%-8% of the global population. Ashwagandha [Withania somnifera (L.) Dunal], a traditional medicine in Ayurveda, is often prescribed for thyroid dysfunctions.

OBJECTIVE: This pilot study was designed to evaluate the efficacy and safety of ashwagandha root extract in subclinical hypothyroid patients.

DESIGN, SETTING, AND PARTICIPANTS: A prospective, randomized, double-blind, single-center placebo-controlled study was performed at Sudbhawana Hospital, Varanasi, India between May 2016 and September 2016. Fifty subjects with elevated serum thyroid stimulating hormone (TSH) levels (4.5-10 μ U/L) aged between 18 and 50 were randomized in either treatment (n = 25) or placebo (n = 25) groups for an 8-week treatment period.

INTERVENTIONS: Ashwagandha root extract (600 mg daily) or starch as placebo. Efficacy Variables: Serum TSH, serum triiodothyronine (T3), and thyroxine (T4) levels.

RESULTS: A total of four subjects (two from each group) withdrew their consent before the second visit. Eight weeks of treatment with ashwagandha improved serum TSH ($p < 0.001$), T3 ($p = 0.0031$), and T4 ($p = 0.0096$) levels significantly compared to placebo. Ashwagandha treatment effectively normalized the serum thyroid indices during the 8-week treatment period in a significant manner (time-effects: TSH [$p < 0.001$], T3 [$p < 0.001$], and T4 [$p < 0.001$]). Four subjects (8%) (ashwagandha: 1[4%]; Placebo: 3[12%]) out of 50 reported few mild and temporary adverse effects during this study.

CONCLUSION: Treatment with ashwagandha may be beneficial for normalizing thyroid indices in subclinical hypothyroid patients.

KEYWORDS: Withania somnifera (L.) Dunal.; ashwagandha; efficacy; safety; subclinical hypothyroidism