# Comparison of Efficacy and Safety of Low- Versus High-Dose Oral Prednisolone in Infantile Spasm (IS): An Open Label Randomized Controlled Trial at the Children's Hospital Institute of Child Health, Multan, Pakistan

**Syed Fawad Saleem Shah ,Faisal Zafar**, ,Abdul Basit , Nuzhat Noreen, Muhammad Yousaf ,

Department of Pediatric Neurology, The Children's Hospital and The Institute of Child Health, Multan, Pakistan

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## Introduction

.Infantile spasm (IS) is known to be an epileptic syndrome described by epileptic spasms, hypsarrhythmia on electroencephalography (EEG), and increased risk of neurodevelopmental regression. The IS is estimated to occur most commonly between age groups of three to 12 months and its overall incidence is between 0.3-0.4 per 1,000 live births while peak age of onset of IS noted to be between four and seven months [1,2]. Various causes of IS are labeled in the literature like structural, genetic, metabolic or perinatal causes [3,4]. Cessation of the spasms is the major aim of the treatment of IS whereas EEG is considered to an efficient tool to evaluate children with IS. Early treatment and cessation of spasm has been linked with improved neurodevelopmental outcomes among children IS [5]. On the other hand, delays in the treatment of IS have been associated with poor outcomes, including psychomotor regression and various other types of seizures in the later years of life.\ Treatments for IS mainly include antiepileptic drugs (AEDs), corticotropic hormones, pyridoxine, and a ketogenic diet [8-10]. Conventional AEDs have been noted to result in unsatisfactory seizure control among children with IS [11,12]. Adrenocorticotropic hormone (ACTH) plays a major role in treating IS by suppressing endogenous corticotropin-releasing hormone (CRH) through a negative feedback pathway.

## Objective

Children with age between three and 24 months who presented with epileptic spasms with a frequency of a minimum 1 cluster/day with EEG confirmed hypsarrhythmia

## Material and Methods

Methodology: This open label randomized controlled trial was conducted at Department of Pediatric Neurology, The Children's Hospital & Institute of Child Health, Multan, Pakistan, from January 1, 2020 to December 31, 2020. A total of 62 children (31 in each group) aged three months to two years presenting with epileptic spasms (at least one cluster per day) with EEG evidence of hypsarrhythmia were included. All 62 children were randomized to receive either high-dose prednisolone (10mg per dose four times a day) or the usual-dose prednisolone (2mg/kg/day thrice a day) for 14 days. Primary outcome measure was noted in terms of proportion of children who achieved complete, partial, or no response. Secondary outcome measure was proportion of children with adverse effects.

## Result

Results: In a total of 62 children, there were 34 (54.8%) male. Overall, mean age was noted to be 9.1±3.4 months. The most common etiology of IS was noted to be hypoxic-ischemic encephalopathy (HIE) in 28 children (45.2%). Significantly better clinical efficacy was reported in high-dose prednisolone group when compared to low-dose prednisolone cases as complete response, partial response and no response were noted in nine (29.0%), eight (25.8%), and 14 (45.2%) patients of low-dose group versus 18 (58.1%), eight (25.8%), and five (16.1%) patients in high-dose group, respectively (p=0.0265). Weight gain was the most frequently reported adverse effects noted in 11 (17.7%) cases. Overall, no statistically significant difference in the frequency of adverse effects (p=0.9573).

## Conclusion

Conclusion: In comparison to low-dose prednisolone, high-dose prednisolone was found to be significantly more efficacious among cases of IS. Adverse effect in both treatment groups were relatively low and similar

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Department of Pediatric Neurology, The Children's Hospital and The Institute of Child Health, Multan, Pakistan.
Email : drfawad898@gmail.com
Contact #: +92 343 8401597