

Vigabatrin With High Dose Prednisolone Combination Therapy vs Vigabatrin Alone for Infantile Spasm

NCT04302116

Status	RECRUITING
Phase	Not Applicable
Sponsor	Kullasate Sakpichaisakul
Enrollment	250 participants

Key Eligibility Criteria

Inclusion (3)

- Age at 2-14 months at date of enrollment
- Clinical diagnosis of infantile spasm assessed by pediatric neurologist and hypsarrhythmic pattern or variants interpreted by pediatric epileptologist
- Thai nationality

Exclusion (6)

- Previous treatment (within the last 28 days) with vigabatrin or corticosteroid
 - Previous diagnosis of epileptic encephalopathy e.g. early infantile epileptic encephalopathy and early myoclonic epileptic encephalopathy
 - Has a clinical suspicious or diagnosis of tuberous sclerosis complex characterized by one of these; known affected parent, previously diagnosed cardiac rhabdomyoma, hypomelanotic macules, forehead fibrous plaque, shagreen patch, retinal phakoma, or known polycystic kidneys
 - A contraindication to vigabatrin or corticosteroid such as recent varicella or herpes zoster infection, gastrointestinal hemorrhage etc.
 - Thai language ability of the parents or guardians is that they may not understand what is being requested of them.
- ... and 1 more (see full listing online)

Locations (1 total)

Queen Sirikit National Institute of Child Health, Ratchathewi, Bangkok, Thailand