

A Real World Study of the Effect of Early PEG-rhGH Therapy on Cognitive Development of SGA Infants

NCT05144035

Status	RECRUITING
Phase	Phase 4
Sponsor	Tongji Hospital
Enrollment	138 participants

Key Eligibility Criteria

Inclusion (9)

- Provide informed consent signed and dated by the subject's legal guardian;
- The subjects met the clinical diagnosis of small for gestational age infants.
- The age ranged from 6 months to 2 years old (including 6 months and 2 years old);
- Height and head circumference are lower than the reference value - 2sd (including-2sd), whose weight is lower than the 10th percentile of the reference value of normal children of the same age and sex;
- The total developmental quotient GQ calculated according to Griffiths mental development scale is less than 100 points (100 points) Indicates that the developmental age is consistent with the physiological age);
- ... and 4 more (see full listing online)

Exclusion (15)

- Patients with abnormal liver and kidney function (ALT \gt 2 times the upper limit of normal value, Cr \gt the upper limit of normal value);
- Severe familial dwarfism (father height \lt 155cm or mother height \lt 145cm);
- Definite neurological defects and / or severe neurodevelopmental retardation (the total development quotient calculated according to Griffiths mental development scale is less than 70), definite syndrome affecting cognitive development; Severe perinatal complications (such as severe asphyxia, sepsis, necrotizing enterocolitis, respiratory distress syndrome with long-term sequelae);
- Genetic metabolic diseases (such as congenital hypothyroidism, phenylketonuria, methylmalonic acidemia);
- Congenital skeletal dysplasia, or moderate or above scoliosis (or scoliosis $\geq 15^\circ$) requiring treatment or claudication;
- ... and 10 more (see full listing online)

Locations (1 total)

Wuhan Tongji Hospital, Wuhan, Wuhan, China