

Prior to Enrolment

- Screen subjects by using inclusion/exclusion criteria
- Provide PISC and obtain written informed consent
- Confirm eligibility, obtain clinical generic and developmental assessment and family history. Complete baseline records.

Randomise

Surgery at age 6 months

Surgery at age 12 months

6 Months

Surgery at 6 months

12 Months

12 month assessment

Surgery at 12 months

3 Years (36 Months)

3 year assessment

5 Years (60 Months)

5 year assessment

End of Follow-up