Background:
The General Anesthesia compared to Spinal anesthesia (GAS) trial was an “observer-blind, international, multi-site, randomized equivalence trial” assessing awake regional anesthesia vs. general anesthesia in infants undergoing herniorrhaphy. Its aim was to assess the effect of a single GA exposure on neurocognitive development. Investigators noticed that enrollment varied widely by study site and overall enrollment was low.

Objective:
To explore the differences in enrollment by study country.

Methods:
Design: retrospective, secondary analysis
Source: enrollment data from GAS trial
Analysis: descriptive statistics

Results:
4023 patients screened by 28 centers in 7 countries
AUS and USA screened 84% of potential subjects
High/Low enrollment: 210 (AUS)/24 (NZ)
Overall Enrollment: 18%
Variability in use of pre-defined exclusion criteria (Fig. 1)
Provider refusals to randomize eliminated ~1/3 of subjects in USA & AUS, fewer in other countries, for reasons see Fig. 2.
Highest rates of parent refusal in USA, AUS & NLD (Fig. 3).
Top reasons were:
- GA preferred (39%)
- Spinal preferred (24%)
- D/N want randomization (14%)

Discussion:
Highlights the need to screen many subjects for adequate enrollment
Assumptions based on pilot data in one country may not apply to other countries
Reinforces value of multi-center studies
Highest rates of surgeon and parent refusals in USA
Differences in parent consent rates suggest different approaches and/or expectations regarding study participation

Conclusion: Different screening practices, different rates of provider refusal and variable rates of parent consent contributed to the enrollment challenges in the GAS trial.