STRIDER NZAUS

A Randomised Controlled Trial of Sildenafil Therapy In Dismal Prognosis Early-Onset Intrauterine Growth Restriction

STRIDER NZAus Update

A number of our final STRIDER mothers remain pregnant with the latest EDD in July. We expect all outcome data to be received by August and we will be working closely with sites to follow up on outstanding data and data queries. **Please ensure that you respond promptly to any data requests** to allow us to have the **study results available by the end of the year.**

STRIDER NZAus Childhood Outcome Study commences

This study aims to determine whether any benefit (or harm) seen in the newborn as a consequence of antenatal sildenafil therapy is sustained, or develops, through childhood providing essential and reliable safety and outcome data on this potential new therapeutic intervention in pregnancy.

All surviving children will be eligible for assessment at 2-3 years and we hope to complete follow up for all children. The intention to conduct follow up was documented in our original submission, the STRIDER NZAus Protocol and the Participant Information Sheet & Consent Form. Partial funding has already been obtained with further grants submitted.

We will be contacting each site to start the process of obtaining local approvals shortly.



2.5 year follow up assessment (±6 months)

Time point aligned with ANZNN follow up for extremely preterm and extremely low birthweight infants. To include:

- <u>Paediatric</u>: neurological examination, hearing and vision assessment, medical history.
- <u>Psychometric testing</u>: Bayley-III assessment where this has not been performed as part of routine follow up.
- Parental questionnaires.

Dr Chris McKinlay conducting the first follow up assessment in Auckland in March with baby 001! Image used with permission.

| STRIDER NZAus Childhood Outcome Study Timeline | |
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| 2016-2017 | Protocol preparation and Ethics submissions New Zealand (complete) |
| March 2017 | First Auckland follow up assessment complete |
| 2017 | Australian ethics submissions and local Governance applications |
| 2017-2019 | STRIDER NZAus Childhood Outcome Study assessments conducted at 2.5 years corrected age |
| 2020 | Data analysis and results publication |
| | Trial sequential STRIDER IPD meta-analysis. Timing is determined by other trials in the Collaboration. It is expected that the UK and NZAus trials will complete childhood outcome assessments first. |
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