STRIDER NZAus

A Randomised Controlled Trial of **S**ildenafil **T**herapy **I**n **D**ismal Prognosis **E**arly-Onset Intrauterine Growth **R**estriction

122 women with severe, early onset IUGR (22^0 - 29^6 weeks) will be enrolled from MFM centres across New Zealand and Australia over the next 2 years.

Please help us recruit women in the Auckland region

STRIDER NZAus is a randomised, placebo controlled trial of sildenafil therapy in severe early onset intrauterine growth restriction being **led by researchers at The University of Auckland.**

Aim: to investigate the effect of sildenafil compared to placebo on the proportion of pregnancies with an increase in fetal growth velocity (measured by expected/observed abdominal circumference ratio).

Investigational Treatment: 25mg sildenafil OR placebo (blinded) as an oral tablet, three times daily continued to delivery or 32^0 weeks gestation, whichever is earlier.

After enrolment regular USS & maternal surveillance will be performed at Auckland City Hospital at 48 hours, days 5, 10, 14 and then weekly. Ongoing care and timing of delivery are determined by each individual clinician.

STRIDER NZAus Collaborating Centres

Auckland Hospital/The University of Auckland
Wellington Hospital
Christchurch Women's Hospital
Women's & Children's Hospital, Adelaide
Royal Women's Hospital, Brisbane
The Mater Mothers Hospital, Brisbane
Royal Prince Alfred Hospital, Sydney
Royal Hospital for Women, Sydney
King Edward Memorial Hospital, Perth
Royal Women's Hospital, Melbourne

Inclusion criteria

1. Singleton pregnancy
2a. At **≥22^0 weeks and ≤ 27^6 weeks: AC measure ≤3rd percentile for GA** (ASUM Campbell Westerway);

OR

2b. At **≥28^0 weeks and ≤ 29^6 weeks: EFW <700g** (Hadlock C)

An USS to confirm eligibility will be carried out at Auckland City Hospital before trial entry.

Exclusion criteria

1. Known major fetal anomaly/syndrome/ congenital infection deemed likely cause for IUGR
2. Known fetal aneuploidy
3. Plan made for termination
4. Maternal disease (e.g. preeclampsia) where it is expected that delivery is necessary within next 48 hrs
5. Any contraindication to sildenafil therapy

A potential therapy for IUGR? Basic science work and a small case control study[1] suggests sildenafil has a positive effect on utero-placental blood flow in cases of IUGR which may subsequently influence fetal growth and allow a delay in delivery and so improve outcomes for babies. Our study aims to assess its effect on in-utero fetal growth velocity but we are also collecting information on neonatal outcomes and plan to follow-up infants during early childhood. Our results will contribute to an international STRIDER IPD Collaboration.

[1] von Dadelszen, P., et al., *Sildenafil citrate therapy for severe early-onset intrauterine growth restriction.* BJOG, 2011. **118**(5): p. 624-8.

There are five individual trials planned including UK, Ireland, Netherlands and Canada. STRIDER NZAus trial is the first to commence recruitment and will make a very important contribution, not just answering our primary question **'does sildenafil affect fetal growth velocity?'** but also **'does sildenafil improve survival and development of babies affected by severe IUGR?'**

If any of the women in your care develop early onset IUGR we would be very happy to discuss their case and assess whether the STRIDER NZAus trial is suitable for them. Once enrolled we would be delighted provide USS assessment and advice on their care as required.

Contact us if you would like more information, copies of patient information sheets or for us to visit your unit/team.

The STRIDER NZAus team: Dr Katie Groom, Prof Phil Baker, Prof Peter Stone, Prof Lesley McCowan

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