STRIDER NZAus

Newsletter 1, March 2014

The first STRIDER NZAus subject has been enrolled!
Dr Katie Groom enrolled the first participant at Auckland Hospital on the 11th March.

STRIDER NZAus is a randomised, placebo controlled trial of sildenafil therapy in severe early onset intrauterine growth restriction. The aim of the trial is to investigate the effect of sildenafil treatment when compared to placebo on the proportion of pregnancies that have an increase in fetal growth velocity (measured by a change in the expected/ observed increase in abdominal circumference per day).

Study drug treatment is double blind. Women will receive either 25mg sildenafil or placebo as an oral tablet, three times daily continued through to delivery or 32^0 weeks gestation, whichever is earlier.

Trial funding is NZD$1000 per participant with a NZD $1000 set-up payment.

Recruits to date
1

Target Enrolment
122

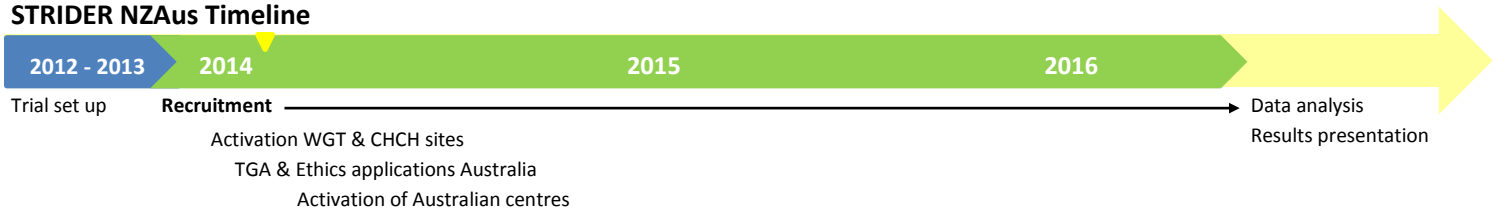
STRIDER IPD Collaboration - STRIDER NZAus is part of an international collaboration with pre-planned Individual Participant Data analysis (IPD) to allow assessment of neonatal outcomes (survival free of major morbidity). Four individual trials are planned: STRIDER NZAus, UK/Ireland (funded), Netherlands (funded) and Canada. The STRIDER NZAus trial is the first to commence recruitment!

Inclusion criteria	Exclusion criteria
1. Singleton pregnancy 2a. At ≥22^0 weeks and ≤ 27^6 weeks: AC measure ≤3rd percentile for GA; OR 2b. At ≥28^0 weeks and ≤ 29^6 weeks: EFW <700g USS measurements for eligibility must have been carried out **≤24 hours prior to randomisation**.	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 hours 5. Any contraindication to sildenafil therapy

Collaborating Centres – we are looking forward to having the following sites on board for the STRIDER NZAus trial

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

STRIDER NZAus Timeline



NZ: Wellington Hospital (Michel Sangalli, Jay Marlow) and Christchurch Women's Hospital (Rosemary Reid) in NZ will be ready to start recruiting within the next 1-2 months.
Australia: we are preparing a multi-centre Ethics application, excl. Perth, with Glenn Gardener acting as Chief Investigator. Jan Dickinson is in the process of preparing the application for KEMH, Perth. The TGA CTN submission is in preparation.

Let us know what we can do to support your site in obtaining your local approvals.

Contact: Dr Katie Groom k.groom@auckland.ac.nz +64 21 2459622; Clinical Trial Manager: laura.mackay@auckland.ac.nz

STRIDER NZAus

Newsletter 2, May 2014

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

STUDY UPDATE

New Zealand Wellington Hospital are now active and on the lookout for their first participant. Christchurch Women's Hospital are on track to start recruiting from June.

Australia Ethics applications have been submitted!

- Multi-site application to RBWH HREC covering all sites QLD, SA, NSW and VIC
  Reviewed 12th May, positive response from the HREC. Minor PICF changes requested & submitted back to HREC.
- Single-site application to WNHS HREC for King Edward Memorial Hospital, Perth
  HREC Committee meeting June 3rd.

A big thank you to **Glenn Gardener**, Chief Principal Investigator, and **Anne Tremellen** at Mater Mothers' and **Jan Dickinson** at KEMH for coordinating these submissions. And to all of our Australian Investigators for sending in signatures and information for your sites.

Completion of the **Site Specific Assessment** is the next step for Australian sites and the team at the Coordinating Centre are here to provide any assistance you might need in preparing these.

Recruits to date

1

Target Enrolment

122

Sites active

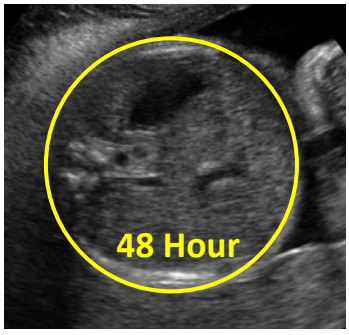
2 / 10

Inclusion criteria	Exclusion criteria
1. Singleton pregnancy 2a. At ≥22^{0} weeks and ≤ 27^{6} weeks: AC measure ≤3rd percentile for GA; OR 2b. At ≥28^{0} weeks and ≤ 29^{6} weeks: EFW <700g USS measurements for eligibility must have been carried out **≤24 hours prior to randomisation**.	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 hours 5. Any contraindication to sildenafil therapy

RANDOMISATION After consent has been obtained eligible subjects are randomised (enrolled) to the trial via a web-based **electronic randomisation** program. An Individual log in will be provided to each site staff member requiring access. A training site is available to carry out practice randomisation and study drug bottle allocation.

The 48 hour Ultrasound Scan – why is it so important?

The STRIDER trial protocol was developed to closely follow standard clinical care for severe IUGR. Routine clinical assessment and scan data should be used wherever possible. One important exception is that around 48 hours after randomisation an ultrasound needs to be performed; this USS **must be between 24 and 72 hours post-randomisation.**



For this population delivery on maternal and/or fetal grounds may be urgently required soon after trial entry. The STRIDER NZAus **primary outcome** has been set as **AC growth velocity** and in order to observe this for each participant it is essential that an ultrasound is carried out shortly after randomisation. The purpose of this scan is to ensure that at least one post-randomisation AC measurement is available to allow calculation of growth velocity; the 48 hour measure will only be used to determine growth velocity if no further scans are performed. This scan will also provide information on any changes in fetal blood flow parameters which may occur as an early treatment effect.

When entering a subject into the trial keep in mind when the 48h scan will fall and schedule this in advance.

CONTACT **Dr Katie Groom, Lead Investigator** k.groom@auckland.ac.nz +64 21 245 9622

Laura Mackay, Clinical Trial Manager laura.mackay@auckland.ac.nz +64 22 4311 988

STRIDER NZAus

Newsletter 3, June 2014

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

STUDY UPDATE

New Zealand Auckland Hospital has recruited a second STRIDER NZAus participant.

Australia

- Ethics Approval has been granted by the RBWH HREC for all sites in QLD, SA, NSW & VIC.
- Single-site application to WNHS HREC for King Edward Memorial Hospital, Perth has been submitted, with outcome pending.
- Research Governance Submissions have been completed by 2 out of 7 sites.

Each Australian site must have HREC approval, research governance approval, a signed contract and have completed a TGA Clinical Trial Notification (CTN) form before starting recruitment. Reach out to the team at the Coordinating Centre if you have any questions about the set up process.

Recruits to date

2

Target Enrolment

122

Sites active

2 / 10

Our goal for STRIDER NZAus is to have the **first Australian centres recruiting in August 2014** and for **all** centres to be **recruiting by November 2014**.
We have the opportunity to be **world leaders** with this novel therapy for IUGR.

Inclusion criteria	Exclusion criteria
1. Singleton pregnancy 2a. At ≥22^{0} weeks and ≤ 27^{6} weeks: AC measure ≤3rd percentile for GA; OR 2b. At ≥28^{0} weeks and ≤ 29^{6} weeks: EFW <700g USS measurements for eligibility must have been carried out **≤24 hours prior to randomisation**.	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 hours 5. Any contraindication to sildenafil therapy

International Collaboration – an update on the STRIDER IPD

STRIDER NZAus is powered to conclusively assess our primary outcome: *"does sildenafil increase AC growth velocity?"* but we are also part of the STRIDER IPD Collaboration. Each individual trial will be independently published and then included in a high quality pre-planned individual patient data meta-analysis sufficiently powered to assess neonatal outcome. In the last month funding approvals have been granted for a new individual trial in Ireland (previously UK/Ireland) and for Canada.

We will now have **five** independent trials contributing to the IPD:

NZAus – recruiting
UK – funded, aim to start recruiting Sept 2014
Netherlands – funded, aim to start recruiting early 2015
Ireland – just funded
Canada – approved for funding

GONet
Global Obstetrics Network

We will make a very significant contribution to this GONet approved IPD analysis

Paediatric funding application STRIDER NZAus

The STRIDER NZAus team is currently preparing a funding application to support follow up of all surviving children through to at least two years of age. Conducting longer term follow up is vital to assessing the effect of sildenafil treatment in-utero on long term health outcomes. This planned follow up is documented in the current protocol and Participant Information Sheet & Consent Form.

CONTACT **Dr Katie Groom, Lead Investigator** k.groom@auckland.ac.nz +64 21 245 9622
Laura Mackay, Clinical Trial Manager laura.mackay@auckland.ac.nz +64 22 4311 988

STRIDER NZAus

Newsletter 4, July 2014

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

Recruits to date

3

Target Enrolment

122

Sites active

2 / 10

STUDY UPDATE

New Zealand Auckland Hospital has recruited a third STRIDER NZAus participant.

Australia

- Research Governance Submissions are underway or have been submitted at most sites.
- A Clinical Trial Notification form (CTN) for each site must be returned to Mater, Brisbane c/o Anne Tremellen before local recruitment can commence. Dr Glenn Gardener at Mater is acting as the sponsor for the TGA submission within Australia.

Reach out to Dr Katie Groom or Laura Mackay, Clinical Trial Manager, at the Coordinating Centre if you have any questions about the set up process. Please provide us with regular updates as you make progress.

	HREC Approval	Hospital Governance Approval	Contract	Active	Subjects Recruited
Auckland Hospital, NZ	√	√	√	**√**	3
Wellington Hospital, NZ	√	√	√	**√**	0
Christchurch Women's, NZ	√	Submitted	In progress	X	-
Royal Women's Melbourne	√	In progress	In progress	X	-
RPA Sydney	√	In progress	Approved & awaiting signatures	X	-
Royal Brisbane & Women's	√	X	In progress	X	-
Women's & Children's Adelaide	√	In progress	Approved & awaiting signatures	X	-
KEMH Perth	Submitted	Submitted	Approved & awaiting signatures	X	-
RHW Sydney	√	In progress	X	X	-
Mater Brisbane	√	Submitted	Approved & awaiting signatures	X	-

Inclusion criteria

1. Singleton pregnancy

2a. At ≥22^{0} weeks and ≤ 27^{6} weeks: AC measure ≤3rd percentile for GA; OR

2b. At ≥28^{0} weeks and ≤ 29^{6} weeks: EFW <700g

USS measurements for eligibility must have been carried out **≤24 hours prior to randomisation**.

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 hours
5. Any contraindication to sildenafil therapy

Recruiting STRIDER NZAus participants to other clinical trials – APTS, FOX, MAGENTA approved

A number of sites taking part in STRIDER across Australia and NZ are active in the FOX, APTS and MAGENTA studies. STRIDER participants have the potential to become eligible for these trials where delivery occurs at <30 weeks (APTS, FOX) or between 30-34 weeks (FOX, MAGENTA). The lead Investigators of FOX, APTS and MAGENTA have given **approval for STRIDER participants to be enrolled providing all other eligibility criteria are met**. If you are taking part in other trials which may overlap with the STRIDER, particularly those which include an investigational drug, and you would like to know if women can be recruited to both please contact us first.

APTS Australian Placental Transfusion Study

The FOX Study (Fetal Oxygenation)

MAGENTA

CONTACT **Dr Katie Groom, Lead Investigator** k.groom@auckland.ac.nz +64 21 245 9622
Laura Mackay, Clinical Trial Manager laura.mackay@auckland.ac.nz +64 22 4311 988

STRIDER NZAus

Newsletter 5, August 2014

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

Recruits to date
4

Target Enrolment
122

Sites active
3 / 10

STUDY UPDATE

New Zealand

- Auckland Hospital has recruited a fourth STRIDER NZAus participant.

Australia

- Mater Mothers' Hospital have governance approval and are now ready to recruit!
- Research Governance Submissions have been submitted by most Australian sites.
- Reminder: a Clinical Trial Notification form (CTN) for each site must be returned to Mater, Brisbane c/o Anne Tremellen for submission to the TGA before local recruitment can commence.

Reach out to Dr Katie Groom or Laura Mackay, Clinical Trial Manager, at the Coordinating Centre if you have any questions about the set up process. Please provide us with regular updates as you make progress.

STRIDER NZAus – Neonatal Outcome Studies

STRIDER NZAus provides a unique opportunity to investigate the effects of maternal sildenafil exposure on the cardiovascular system of the neonate and we are very pleased to have had enthusiasm from several neonatologists in developing a neonatal sub-study. The main focus is cardiovascular function measured by Echocardiogram at 24 hours and 3 days after birth and then at 36 weeks corrected Gestational Age (CGA); and NTpBNP at birth, 3 days and at 36 weeks CGA. PeaPod body composition and aortic intimal thickness are additional measurements that sites can contribute to (if available).

This substudy is an **optional** component of STRIDER NZAus, both for the site and the parents. All sites will be invited to consider taking part in this valuable research and we plan to approach your site and your local neonatologists regarding this substudy within the next few weeks. Applications are underway to source funding. Once we have an indication of which sites may take part this will be submitted as an amendment to each of the responsible Ethics Committees.

For more information contact the Neonatal Investigators leading this study:

Sarah Harris, Christchurch, sarah.harris@otago.ac.nz and Andy Gill, Perth, Andy.Gill@health.wa.gov.au

Inclusion criteria	Exclusion criteria
1. Singleton pregnancy 2a. At ≥22^0 weeks and ≤ 27^6 weeks: AC measure ≤3rd percentile for GA; OR 2b. At ≥28^0 weeks and ≤ 29^6 weeks: EFW <700g USS measurements for eligibility must have been carried out **≤24 hours prior to randomisation**.	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 hours 5. Any contraindication to sildenafil therapy

	HREC Approval	Hospital Governance Approval	Contract	Active	Subjects Recruited
Auckland Hospital, NZ	√	√	√	**√**	4
Wellington Hospital, NZ	√	√	√	**√**	0
Christchurch Women's, NZ	√	x	√	X	-
Royal Women's Melbourne	√	Submitted	In progress	X	-
RPA Sydney	√	In progress	Approved & awaiting signatures	X	-
Royal Brisbane & Women's	√	In progress	In progress	X	-
Women's & Children's Adelaide	√	Submitted	Approved & awaiting signatures	X	-
KEMH Perth	Submitted	Submitted	Approved & awaiting signatures	X	-
RHW Sydney	√	In progress	In progress	X	-
Mater Brisbane	√	√	√	**√**	0

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STRIDER NZAus

Newsletter 6, September 2014

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

Recruits to date
4

Target Enrolment
122

Sites active
4 / 10

STUDY UPDATE

New Zealand

- Christchurch Hospital is now up and running and on the lookout for their first recruit!
- Recruitment is ongoing at Auckland and Wellington Hospital are actively screening.

Australia

- Research Governance Submissions have been submitted by most Australian sites.
- Reminder: a Clinical Trial Notification form (CTN) for each site must be returned to Mater, Brisbane c/o Anne Tremellen for submission to the TGA before local recruitment can commence.

We are looking forward to having the remainder of the Australian sites on board soon!

	HREC Approval	Hospital Governance Approval	Contract	Active	Subjects Recruited
Auckland Hospital, NZ	√	√	√	**√**	4
Wellington Hospital, NZ	√	√	√	**√**	0
Christchurch Women's, NZ	√	√	√	**√**	0
Royal Women's Melbourne	√	Submitted	In progress	X	-
RPA Sydney	√	Submitted	Approved & awaiting signatures	X	-
Royal Brisbane & Women's	√	In progress	In progress	X	-
Women's & Children's Adelaide	√	Submitted	Approved & awaiting signatures	X	-
KEMH Perth	Submitted	Submitted	Approved & awaiting signatures	X	-
RHW Sydney	√	In progress	In progress	X	-
Mater Brisbane	√	√	√	**√**	0

Inclusion criteria

1. Singleton pregnancy

2a. At ≥22^{0} weeks and ≤ 27^{6} weeks: AC measure ≤3rd percentile for GA; OR

2b. At ≥28^{0} weeks and ≤ 29^{6} weeks: EFW <700g

USS measurements for eligibility must have been carried out **≤24 hours prior to randomisation**.

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 hours
5. Any contraindication to sildenafil therapy

Here is STRIDER NZAus baby number 2! He is now ten weeks old and thriving in NICU but having been born at 30 weeks weighing just 795g he's had a rocky road.

I have always found counselling parents-to-be of early onset severely growth restricted babies a bit depressing. Looking for other causes and then lets 'wait and see' is not much to offer and hard for everyone to cope with when prognosis may be so poor. Over the last few months I have not changed my counselling that much but have found it such a relief to end my counselling with a little ray of hope. Not every woman wants to be in STRIDER NZAus, not every woman taking part in the trial will be on sildenafil and it may not be the answer to this problem but women have been genuinely pleased to hear we are trying to improve the outlook for the future.

So far in Auckland we have identified nine women potentially suitable for the study, of which after further assessment seven have been eligible and four have agreed to take part. Everyone has been very interested and willing to hear about the study. Those involved have very happily attended for all study reviews and been reassured by the level of surveillance they have received. They've also had fun trying to guess whether they are on active treatment or not – I guarantee a few husbands will offer comment!

We really hope your site will be live, screening and recruiting soon so you can join us offering this valuable trial to women in your hospital too.

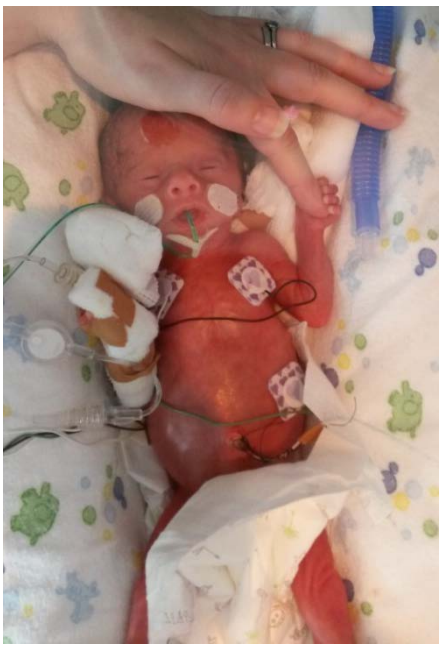

Image used with permission

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STRIDER NZAus

Newsletter 7, October 2014

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

A CHALLENGE IS SET. We are making good progress in getting all Australian centres up and ready to recruit. Thank you to you all for your commitment to making this happen. So here is the next challenge……

The first recruit from outside Auckland please.
The race is on for you all to win this accolade!

For those of you still to be 'live' and recruiting let us know what we can do to help to get your governance over the line.

Those of you who are screening for eligible women please start to think about ways you might widen your net to find all eligible women. Maybe circulating our newsletters more widely, an email reminder to your department, info flyer to private obstetricians and local USS centres. If we can help to prepare any resources just let us know.

Paediatric funding application STRIDER NZAus – through the first round

We have successfully made it through the first round of the HRC NZ funding application process to support longer term follow up of all surviving STRIDER NZAus children. Chris McKinlay and Frank Bloomfield, neonatologists based in Auckland, are on board for the Follow Up team. If the funding application is successful we will be making contact with your neonatal colleagues to arrange the paediatric follow up. This will be funded separately and will not require additional work from your obstetric team. Results will be announced June 2015.

	HREC Approval	Hospital Governance Approval	Contract	Active	Subjects Recruited
Auckland Hospital, NZ	√	√	√	**√**	4
Wellington Hospital, NZ	√	√	√	**√**	0
Christchurch Women's, NZ	√	√	√	**√**	0
Royal Women's Melbourne	√	Submitted	In progress	X	-
RPA Sydney	√	Submitted	Approved & awaiting signatures	X	-
Royal Brisbane & Women's	√	In progress	In progress	X	-
Women's & Children's Adelaide	√	Submitted	√	X	-
KEMH Perth	√	√	√	X	-
RHW Sydney	√	In progress	Approved & awaiting signatures	X	-
Mater Brisbane	√	√	√	**√**	0

STUDY UPDATE - AUSTRALIA

- **Congratulations to Professor Jan Dickinson**, KEMH Perth, for obtaining Ethics and Governance approval this month! Site activation for KEMH is just days away.
- Laura and Katie had a great visit to Adelaide this month to launch STRIDER. We are pleased to hear Peter Muller at Women's and Children's Hospital has successfully wrangled the local governance requirements and will be recruiting in the next 1-2 weeks.

Recruits to date
4

Target Enrolment
122

Inclusion criteria

1. Singleton pregnancy

2a. At ≥22^{0} weeks and ≤ 27^{6} weeks: AC measure ≤3rd percentile for GA; OR

2b. At ≥28^{0} weeks and ≤ 29^{6} weeks: EFW <700g

USS measurements for eligibility must have been carried out **≤24 hours prior to randomisation**.

Exclusion criteria

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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 hours
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STRIDER NZAus

Newsletter 8, November 2014

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

*****BIG NEWS*****

Congratulations to Rosemary Reid, Di Leishman and the team at Christchurch Women's, NZ, for recruiting their first and second participant all in the same week!

These are the first participants to be enrolled **outside of Auckland** and mark a significant milestone for the STRIDER NZAus trial. Di Leishman, research midwife, expressed how rewarding it was to have successfully randomised the first women into the trial after months of set up and preparation to obtain local hospital approval.

At Auckland Hospital we have also been busy, randomising **three** women to the trial in November marking our highest monthly recruitment to date.

The next **CHALLENGE** for STRIDER NZAus is the **first Australian participant**……. Will it be the Mater Brisbane, King Edward or possibly WCH, Adelaide or the Women's in Melbourne?

Recruits to date
9
Target Enrolment
122

STRIDER International Trials IPD Update

The STRIDER UK trial went 'live' recently. Their first recruit has just been enrolled. The other individual STRIDER trials that make up the IPD group are expected to start recruitment throughout 2015.

	HREC Approval	Hospital Governance Approval	Contract	Active	Subjects Recruited
Auckland Hospital, NZ	√	√	√	√	7
Christchurch Women's, NZ	√	√	√	√	2
Wellington Hospital, NZ	√	√	√	√	0
Mater Brisbane	√	√	√	√	0
KEMH Perth	√	√	√	√	0
Women's & Children's Adelaide	√	Submitted	√	X	-
Royal Women's Melbourne	√	Submitted	In progress	X	-
RPA Sydney	√	Submitted	Approved & awaiting signatures	X	-
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STRIDER NZAus

Newsletter 9, December 2014

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

Happy holidays from the STRIDER NZAus team

Katie will be available throughout the holiday period for any urgent or participant related queries **k.groom@auckland.ac.nz** **+64 21 245 9622**

Recruits to date
11 / 122

****BIG NEWS 1st Australian recruit****

Congratulations to Professor Jan Dickinson and the team at King Edward Memorial Hospital, Perth, for this achievement!

It has been wonderful to see trial recruitment on a steady increase over the last few months as more sites have started actively recruiting and a real reward for all of the hard work that goes into set up at each hospital.

Mater Mothers' in Brisbane have been actively screening and although the first two candidates were unable to take part we are sure it will be third time lucky! Early 2015 will see recruitment commencing at Women's and Children's Hospital in Adelaide, PI: Dr Peter Muller, and The Royal Women's in Melbourne, PI: Dr Julia Unterscheider.

We are continuing to work with Jon and Marilena at RPA Sydney, Renuka, Margo and Lisa at Royal Brisbane & Women's, Alec and Anne at RHW Sydney to progress the local approvals for the trial so recruitment can get underway.

	HREC Approval	Hospital Governance Approval	Contract	Active	Subjects Recruited
Auckland Hospital, NZ	√	√	√	**√**	8
Christchurch Women's, NZ	√	√	√	**√**	2
KEMH Perth	√	√	√	**√**	1
Wellington Hospital, NZ	√	√	√	**√**	0
Mater Brisbane	√	√	√	**√**	0
Women's & Children's Adelaide	√	√	√	Pending	-
Royal Women's Melbourne	√	√	√	Pending CTN	-
RPA Sydney	√	Submitted	Approved & awaiting signatures	X	-
Royal Brisbane & Women's	√	In progress	In progress	X	-
RHW Sydney	√	In progress	Approved & awaiting signatures	X	-

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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 hours
5. Any contraindication to sildenafil therapy

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