Newsletter May 2015

LCTU
Liverpool Clinical Trials Unit

Liverpool Women's NHS
NHS Foundation Trust

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National Institute for Health Research

UNIVERSITY OF LIVERPOOL

A Randomised Controlled Trial of sildenafil therapy In Dismal Prognosis Early-Onset Intrauterine Growth Restriction

EudraCT: 2013-005398-32 ISRCTN: 39133303 UKCRN:16986 Chief Investigator: Professor Z Alfirevic

Dear all

We are going from strength to strength with the STRIDER trial and now have 32 patients recruited from our 112 target

This is all due to your hard work in identifying and approaching potential participants and your enthusiasm for STRIDER.

With recruitment going so well and most centres now open we need to ensure that the quality of data recorded is as good as it can be.

We are constantly evolving our systems and if you have any personal ideas about what we can do better please just let us know and we will see if we can incorporate them.

The trial website: www.stridertrial.co.uk has had an overhaul and you can now find extra content including links to our PPI collaborators, patient centred slides, regular updates of recruitment and previous newsletters.

We will be adding more comments from our PPI collaborators soon (ARC and SANDS). We would also like to ask you to approach your participants to see if they would wish to give a personal recommendation of their involvement as a patient in the STRIDER trial and we could add these to the website as well

We have also opened our first Twitter account for the trial and please feel free to follow us and pass this to your patients as well @StriderTrialUK

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Finally we thought now would be a good time to highlight the reporting of serious adverse events (SAEs).

Whilst we hope these will be few in number, by the nature of the high risk pregnancies included in STRIDER it is likely we will have some SAEs should be reported to the trial coordinator (Sarah Quinby) at the LCTU by phone (0151 794 8292) or email (strider@liverpool.ac.uk) within 24 hours of the PI becoming aware of them.

SAE forms can be found on the LCTU portal in the investigator site file under section 13 (SAEs)

Whilst we have endeavoured to catch most potential SAEs by routinely collected information on the eCRF the following examples should be used to guide reporting of SAEs

Fetal

Intrauterine fetal death following administration of IMP (SAE – report sent to trial coordinator)

Emergency caesarean section for abnormal fetal monitoring (not SAE, recorded on eCRF form)

Maternal

Maternal ECG or cardiac marker evidence pf cardiac event (SAE – report sent to trial coordinator)

Maternal venous thromboembolic event (SAE – report sent to trial coordinator)

Development of pre-eclampsia (not SAE, recorded on eCRF form)

Flushing post IMP administration (not SAE, recorded on eCRF form)

Neonatal

Unexpected fetal anomaly (SAE – report sent to trial coordinator)

Prolonged admission to neonatal intensive care secondary to IUGR and/or prematurity (not SAE, recorded on eCRF form)

Neonatal death (SAE – report sent to trial coordinator)

Thank you

The STRIDER team

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STRIDER Team:

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Recruiting Sites

Site name	Site Initiation Completed	Site Open	Patients Randomised
Liverpool Women's	Yes	Yes	5
St Mary's Hospital, Manchester	Yes	Yes	14
St George's Hospital London	Yes	Yes	0
Leicester Royal Infirmary	Yes	In Process	0
John Radcliffe Women's Centre, Oxford	Yes	Yes	3
Birmingham Women's Hospital	Yes	Yes	2
University Hospital of North Staffordshire	Yes	Yes	0
Heartlands Hospital, Heart of England	Yes	Yes	2
St Michaels Hospital, University Hospitals Bristol	Yes	In Process	0
Royal Victoria Infirmary Newcastle—upon—Tyne Hospital	Yes	Yes	0
University College London	Yes	Yes	0
Leeds General Infirmary	Yes	Yes	1
Norfolk and Norwich University Hospital	Yes	Yes	2
Nottingham University Hospitals	Yes	Yes	1
University of Edinburgh MRC Centre for Reproductive Health	Yes	Yes	0
Kings College London	Yes	Yes	1
Guy's and St Thomas Hospital London	Yes	Yes	1
Princess Anne Southampton	Yes	In Process	0
NHS Fife Victoria Hospital	Yes	In Process	0
Barts London	TBC	In Process	0

We would like to take a moment to thank all investigators and study staff for their interest and motivation in the STRIDER Study.

We look forward to reaching our 112 patient recruitment target.

Thank you