WILL Trial

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WILL is open to pilot sites!

Hello, welcome to our first edition of the WILL Trial Newsletter. We have been thrilled with the high number of sites that have expressed an interest in participating in WILL.

Thank you to all of the sites that have filled out the feasibility and survey of practice forms so far. We have been looking through them all and seeing a wide variation in practice (one of the reasons why we need the WILL trial!).

What next?

Our plan with NIHR is that we will run a 9-month internal pilot trial, starting this month. We are contacting sites to invite them to take part in the pilot phase, based on needing a variety of site locations and sizes. We plan for the main phase of the Trial to begin in late September/October with a view to starting recruitment in late November 2019. Therefore, we are very keen to maintain contact with all sites that have shown interest in participating in WILL.

What is WILL?

WILL aims to investigate the clinical effectiveness and cost-consequences of planned early term delivery at 38+0 to 38+3 weeks, compared with expectant care at term until at least 40+0 weeks, in pregnant women with chronic or gestational hypertension that develops by 37+6 weeks.

Why 'WILL'?

William (Will) is the Chief Investigator's youngest child. Her other two children have had studies named after them (i.e., EMMA and PIERS), and now Will does too.

Recognise the logo?

It is based on the CHIPS trial logo (Control of Hypertension In Pregnancy Study). The UK was the #1 recruiting country in CHIPS that enrolled women with chronic or gestational hypertension, just like WILL. CHIPS was designed to study how we should treat hypertension.

WILL is designed to determine when they should give birth to optimize outcomes for mothers and babies..

Happy April Fools Day

Participating sites

WILL co-ordinating Research Midwives

Sue and Julie are the WILL Lead Research Midwives. They, along with all other members of the WILL trial team, will provide you with the support that you need.

Sue will be covering the South participating sites, and Julie will be covering North participating sites.

Site initiation visits (SIVs)

We have visited the following sites to facilitate Site Initiation Visits:

* St Thomas' Hospital, London
* St James University Hospital, Leeds
* Bradford Royal Infirmary Hospital
* Liverpool Women's Hospital
* Croydon University Hospital

Next month, we are going to facilitate a SIV at West Middlesex University Hospital, Birmingham Women's Hospital, and Nottingham Hospitals.

Updates:

We plan to hold monthly telephone conferences so that we can discuss any issues and share successes with sites. Please do let us know how we can best support you. We are very keen to hear your views!

FAQ's

Q: Why are we consenting at 36 weeks but not randomising until 37 weeks?

A: We are consenting from 36+0 weeks to give a two-week window for consent, particularly because women will not necessarily be seen twice during this period. Consent requires a face-to-face conversation, whereas reconfirmation of eligibility and randomisation can be done remotely (such as over the phone). Also, we want to give teams enough time to book the induction if the woman is allocated to planned early term delivery (and the plan is not for an elective Caesarean for other reasons).

Q: Are women still eligible if their BP is within a normal range, even though they have been diagnosed with chronic or gestational hypertension and meet all of the eligibility criteria?

A: Yes, these women are eligible as long as they have a diagnosis of chronic or gestational hypertension, as they do NOT need to be hypertensive or on antihypertensive medication at the time of recruitment.

Happy Easter!