NHS SCOTLAND
NHS RESEARCH SCOTLAND
REPRODUCTIVE HEALTH AND CHILDBIRTH

Update from NRS Reproductive Health and Childbirth Specialty Group

July 2021

Bee Orchid, *Ophrys apifera*

THE LOCI TRIAL NEEDS YOUR SUPPORT!

Letrozole Or Clomifene for Ovulation Induction. CPMS 42795, IRAS 257918.
Chief Investigator: Professor Arri Coomarasamy, University of Birmingham.

NHS Grampian and Lothian are already recruiting.
We need other Health Boards to recruit to this important trial!

LOCI is a Phase III double blinded trial investigating whether Letrozole is a suitable alternative to Clomifene, with or without metformin, for ovulation induction in women with polycystic ovary syndrome: a 2x2 factorial design randomised trial. This NIHR Portfolio trial has been significantly impacted by the COVID-19 pandemic as acknowledged by the funder (NIHR HTA). However, they have asked for the trial to more than double recruitment from 25-30 per month to 75 by Oct-2021. This outcome would be devastating news for patients and the NHS.

The recruitment numbers have been increasing steadily on a month-by-month basis, and so we feel that we can reach the target and save this trial. However, this would require a truly concerted effort from every PI, and every research nurse. **Every single participant who is recruited is now essential for our survival. Could I (the CI) therefore please ask for your help and support at this hour of need? We need your site open to LOCI please!**

The Trial team have a dedicated clinical fellow who would be able to travel to your site to share knowledge, troubleshoot and provide any necessary assistance.

Any issues please contact Abha / Txaro

NHS Research Scotland - confidence in research survey

The Chief Scientist Office is interested in the public's view on whether the vaccine programme influences patient confidence on returning to, or starting participation, in research studies. Responses will help the recovery of research across NHS Scotland. Below is the link to the survey, please distribute widely.
https://www.surveymonkey.co.uk/r/confidenceinresearch

NHS Research Scotland Amendments

Effective management of amendments to research studies: Principles for UK approach.

This approach for the management of amendments relates to changes made to a research study after HSC/NHS Research and Development (R&D) permission (Scotland/Northern Ireland) or HRA and HCRW Approval (England/Wales) is granted. These amendments may be 'substantial' or 'non-substantial', which is determined by the sponsor of the research study. The amendment tool will help sponsors make this decision. Full document

Amendments Update. The process for how participating nations are notified of new amendments has changed. This change was implemented as email notifications were not always being sent by the lead nation. NRS Permissions Coordinating Centre (NRS PCC) are now working through any amendments Scotland should have received over the past few months. Full document

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REPRODUCTIVE HEALTH AND CHILDBIRTH

Please send your Good News, queries or feedback:
Abha (abha.maheshwari@abdn.ac.uk) or
Txaro (maria.amezaga@nhs.scot)

NEW STUDY

Public Health Scotland | 1495 UNIVERSITY OF ABERDEEN | University of Dundee

Perinatal experiences during the Covid-19 pandemic in Scotland: exploring the impact of changes in maternity services on women and staff. IRAS 289009.
Chief Investigator: Dr Albert Farre, University of Dundee.
Sponsor: University of Dundee. Funder: Public Health Scotland.

As NHS Scotland maternity services have changed dramatically during the Covid-19 pandemic, PHS have commissioned research to explore the experience of the changes for pregnant and postnatal women (from 36 weeks pregnant to 12 months postnatal), and healthcare staff. This mixed-methods project will identify how changes have been perceived by women and staff according to their personal or professional background respectively. It will seek to understand the barriers and facilitators to use of maternity care during the pandemic.

The methods will include a survey (led by Dr Mairead Black at University of Aberdeen) and qualitative interviews (led by Dr Albert Farre at University of Dundee). Data triangulation will occur at several points. The findings will help shape the next Scottish Government maternity services policy update.

STUDY LOOKING FOR NEW SITES

WILL Trial. When to Induce Labour to Limit risk in pregnancy hypertension – a multicentre, randomised controlled trial. CPMS 39805, IRAS 252294.
Chief Investigator: Professor Laura Magee, King's College London. Funder: NIHR HTA.

WILL is a pragmatic RCT which aims to address optimal timing of birth for women with hypertension in pregnancy. Please see Protocol for more details.
Following a successful pilot phase, the trial has been granted permission to enter the main phase of recruitment and the trial team are looking to extend site opening across the UK.
The trial is designed to be conducted remotely from consent, randomisation and through to follow up so it is an ideal trial for teams who are facing the challenge of healthcare research in the midst of a pandemic.

Please let us know if you or colleagues are interested in participating and please complete the WILL Feasibility Survey and WILL Survey of Practice, this will help the team to advise how best to implement the WILL protocol at your site.
For further details please contact the Senior Trial Manager, Katie Kirkham, K.L.Kirkham@bham.ac.uk

REPRODUCTIVE HEALTH & CHILDBIRTH STUDIES. PORTFOLIO UPDATE.

See list of Eligible studies which are Active in Scottish sites (i.e. active in at least one Health Board) and those COVID-19 New Recruitment Suspended, data cut 07/07/2021. Click here
Eligible studies are supported by a funder which appears on the CSO Eligible Funders list

For information about studies in the Portfolio or any queries please contact Abha or Txaro.