



# 1<sup>ST</sup> CLASS DELIVERY

*Newsletter Issue 1, March 2020*

[cope@liverpool.ac.uk](mailto:cope@liverpool.ac.uk)



[www.cestudy.uk](http://www.cestudy.uk)



0151 795 8760



## STUDY OVERVIEW

- **Aim:** To determine if carboprost or oxytocin is more effective as 1<sup>st</sup> line PPH treatment
- Target of **3,948** women across **40** UK hospitals
- Expected first recruit – **August 2020**

## COPE KITS UPDATE

### ***COPE kit delivery to sites now expected in August 2020***



**Left:** Oxytocin (ISO standard ampoule)  
**Right:** Carboprost (Hemabate) (non-ISO standard ampoule)

Delays in opening to recruitment have been due to problems faced in maintaining the investigational medicinal product (IMP) blinding. In COPE, carboprost is administered intramuscularly (IM) and oxytocin intravenously (IV), so each needs a corresponding placebo in order to maintain the blinding. Each woman will therefore receive an intramuscular injection and an intravenous injection, one of which will be placebo (0.9% sodium chloride) and the other an active drug (carboprost or oxytocin). As carboprost and oxytocin are contained within different shaped ampoules, two different shaped ampoules will be contained within each kit.

The production of oxytocin placebos is simple as oxytocin is contained within an ISO standard ampoule that can be procured off the shelf. However, the production of a carboprost placebo is difficult as carboprost is contained within a non-ISO standard ampoule.

The carboprost placebo ampoules have been custom made for COPE. The machinery used to fill and wash the ampoules require bespoke machine parts in order to support the uniquely shaped ampoules.

## SITE TRAINING

Site Name	Date
Liverpool Women's Hospital	19/07/2019
Sunderland Royal Hospital	30/08/2019
Birmingham Women's Hospital	09/10/2019
Burnley General Hospital	11/10/2019
Guy's & St Thomas Hospital	17/10/2019
Leeds University Hospitals	06/11/2019
Stepping Hill Hospital	11/11/2019
Kingston Hospital	13/11/2019
University College London Hospital	18/11/2019
Bradford Royal Infirmary	25/11/2019
St Mary's Hospital, Manchester	02/12/2019
Royal Victoria Infirmary	05/12/2019
University Hospital of North Tees	05/12/2019
Whittington Hospital	10/12/2019
Queen Elizabeth Hospital, Gateshead	12/12/2019
Medway Maritime Hospital	17/12/2019
Wrexham Hospital	20/12/2019
Royal Hallamshire Hospital	22/01/2020
Peterborough Hospital	27/01/2020
Hinchingbrooke Hospital	27/01/2020
West Middlesex University Hospital	04/02/2020
Poole Hospital	26/02/2020
Nottingham University Hospitals	09/03/2020
Milton Keynes University Hospital	23/03/2020
John Radcliffe Hospital	18/05/2020

## COPE SITE MAP



### SITE CHECKLIST

- Completed site training visit (STV)
- CVs & GCPs for all delegated staff, signed and dated within the last 3 years sent to LCTC
- Completed site suitability questionnaire
- Confirmation of Capacity & Capability in England, or R&D approval in Scotland
- Agreed & executed Research Site Agreement
- Dissemination training of recruiters & other staff not at STV
- Site sensitisation talks

**JUNE  
2020**

### INVESTIGATOR MEETING

In June 2020 we plan to hold a Principal Investigators meeting in Liverpool. The aim of this meeting will be to share ideas and gear sites up for recruitment start in August 2020.

## EMBEDDED QUALITATIVE STUDY

- For at least the first 9 months of recruitment, we will use different methods to explore the views and experiences of women recruited to the trial and their birth partners.
- Interim findings from this research will be used to inform approaches to recruitment and consent procedures for the remainder of the COPE trial.

Tasks	Pilot Sites*	All other sites
Part A – Audio Recorded recruitment discussions	✓	✗
Part B – Questionnaires with women and birth partners (consenters <b>and</b> decliners)	✓	✓
Part C – Interviews with women and their birth partner (consenters <b>and</b> decliners)	✓	✓
Part D – Staff focus groups and/or PI interviews	✓	✗

\*Pilot sites: Liverpool Women's Hospital, Birmingham Women's Hospital, Guy's & St Thomas' Hospital, Sunderland Royal Hospital, University College London Hospital.

## GETTING READY FOR SITE OPENING



**CERTIFICATE of ACHIEVEMENT**

NHS  
National Institute for  
Health Research

Staff involved in obtaining consent post randomisation (for women recruited via emergency pathway) require **Informed Consent with Adults lacking Capacity GCP** training in addition to secondary care GCP training. This course takes approx. 20 mins and can be found online along with other [NIHR GCP courses](#)

### As COPE is an emergency trial, a pragmatic approach to training will be adopted:



It is advised that a sufficient number of doctors (recruiters) are listed on the delegation log as able to “confirm eligibility” to ensure that recruitment targets are met. Staff who administer the COPE IMP under the supervision of the recruiter (recruiter must be a medic) do not require COPE training and will not be delegated duties on the delegation log, as this will be in line with routine practice.



COPE support staff involved in assessment of eligibility (not formal confirmation of eligibility), completion of assessment of eligibility form, collection of COPE treatment kits (randomisation) and IMP accountability will not be delegated duties on the delegation log; they will be COPE trained only (recorded on a separate COPE training log). Staff not listed on the delegation log are not required to provide GCP or CV certificates.

**Site training visits carried out by the central COPE team to the core site team should be disseminated by the PI or co-I to the remainder of the team in good time prior to August 2020. For newly rotated doctors that may start following August, some sites are tying in COPE and GCP training in their inductions.**

**Professor Andrew Weeks**  
COPE Chief Investigator  
University of Liverpool  
Liverpool Women's Hospital



## MESSAGE FROM TEAM COPE

Team COPE would like to say a big thank you to all sites for their interest in COPE and hard work in organising and hosting training visits. We really appreciate all of the thought that is going into logistics at site and all of the work towards site greenlight whilst the COPE kits are being made. We believe that all of your enthusiasm will help to make recruitment as efficient as possible when the COPE kits are ready.

We hope that come August we can hit the ground running, and in the meantime please do not hesitate to get in touch.