Effect of combined contraceptive pills on exclusive breastfeeding and infant weight gain; a double-blind randomized clinical trial of combined and progestogen-only pills with an observational control group of IUD users

**Current Project Brief**

**Objectives and Background**
To provide quality information on effects of combined oral contraceptives (COCs) on exclusive breastfeeding performance and infant weight increase in the postpartum period to improve the evidence-base and thereby facilitate making evidence-based recommendations on use of COCs during postpartum breastfeeding.

The uncertainty and controversy about the safety of COCs during breastfeeding can only be resolved through attaining high quality data from a double-blinded randomized control trial (RCT) on effect of COCs on breastfeeding, adding an observational control group of women using IUD during breastfeeding.

The protocol is under review at the WHO Ethical Review Committee and the selection of the implementing partners is in progress.

**Geographic location**
It is planned to use 4 settings in both developed and developing countries

**Main deliverables**
This will be a multicentre double-blind RCT in which healthy, exclusively breastfeeding women with singleton healthy infant, born after full-term pregnancy, will be enrolled after consenting to be randomized either to COCs (30 µg ethinylestradiol, 150 µg levonorgestrel) or to POPs (30 µg levonorgestrel) starting treatment after 6 completed weeks postpartum. Additionally, exclusively breastfeeding women choosing copper IUD for contraception will, after consent, be enrolled and frequency-matched by parity (nulliparity, parity 1+) and age (5 year-of-age bands) to every second woman randomized to COC or POP.

The main outcome variable will be “exclusive breastfeeding” and weight of infant.

**Partners**
Selection in progress

**Sources of funding**
HRP

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