PITCH - Pregnancy Intervention Trial in Cholestasis

Potential study participant identified by clinician and referred to researchers

24<sup>+</sup> – 34<sup>+</sup>
- Consent to UDCA versus placebo
- Baseline bile acid and liver enzymes
  Research sample* if consented
- Randomise to UDCA versus placebo
- Weekly follow-up + compliance questionnaire + clinical and research samples*
- If undelivered at 34<sup>+</sup> to 37<sup>+</sup>, consent to delivery versus delay
- Randomise to delivery by 37 weeks versus await spontaneous term delivery
- Staff/researchers complete outcome form (Appendix C) following delivery + research samples**
- Follow-up 6 weeks post delivery, complete outcome form (Appendix D) + clinical and research bloods*

34<sup>+</sup> – 37<sup>+</sup>
- Consent to both trials
- Baseline bile acid and liver enzymes
  Research sample* if consented
- Randomise both trials
- Weekly follow-up + compliance questionnaire + clinical and research samples*
- Staff/researchers complete outcome form (Appendix C) following delivery + research samples**
- Follow-up 6 weeks post delivery, complete outcome form (Appendix D) + clinical and research bloods*

≥38<sup>+</sup>
- Only offered UDCA versus placebo
- Consent
- Baseline bile acid and liver enzymes
  Research sample* if consented
- Randomise UDCA versus placebo
- Weekly follow-up + compliance questionnaire + clinical and research samples*
- Staff/researchers complete outcome form (Appendix C) following delivery + research samples**
- Follow-up 6 weeks post delivery, complete outcome form (Appendix D) + clinical and research bloods*

Research sample*: Blood sample for DNA extraction (optional, if participant consents)
Research sample**: Placental sample and cord blood sample (optional, if participant consents)