Giant PANDA
Pregnancy ANtihypertensive Drugs: which Agent is best?

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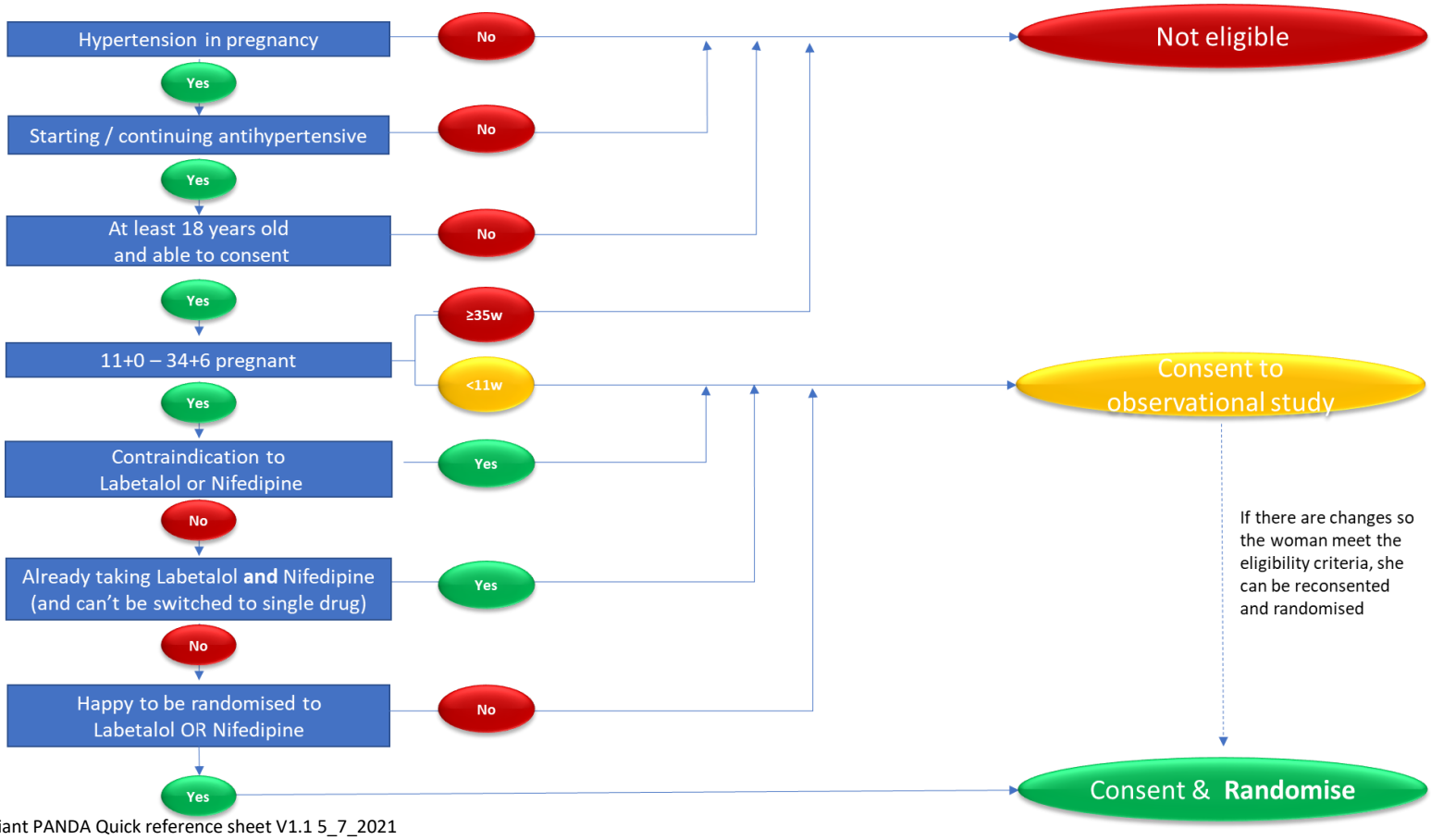
BACKGROUND & RATIONALE FOR TRIAL

- Labetalol and Nifedipine—both have been widely used by pregnant women in the UK for many years and are considered safe to use in pregnancy
- Prescribing varies widely around the country because we do not know which one works best
- Understanding which of these medications are better for the woman without worsening the outcomes of the baby has remained an unanswered research recommendation by NICE since 2010 and was reiterated in the 2019 update

OBJECTIVES

- To evaluate if treatment with nifedipine (calcium channel blocker), compared to labetalol (mixed alpha/beta blocker) in women with pregnancy hypertension, reduces severe maternal hypertension without increasing fetal or neonatal death, or neonatal unit admission
- Investigate other secondary maternal and fetal/neonatal outcomes including patient-reported outcome measures and evaluate cost-effectiveness

ELIGIBILITY



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STUDY PATHWAY

REDCap® Research Electronic Data Capture

Identifying women who may be suitable/eligible & approach them to ask if they wish to participate in the trial

Informed e-consent

Baseline eCRF completion

Woman's Survey – 5-10 mins (auto)

Randomise

via the database (available 24/7) https://bctu-redcap.bham.ac.uk/redcap_v10.3.7/index.php?pid=148

- LAST RESORT: By phone - BCTU randomisation line ((0044) 0800 953 0274) (available Monday – Friday 9-5pm)

Prescribe medication using usual local method (paper or electronic)

Usual antenatal care pathway underpinned by NICE 2019 guidelines (including guidance and support on treatment regimen, for titration of antihypertensive drugs)

Post randomisation contact / safety check by RM – after 2 weeks

1. Safety check

2. Woman's Survey – 30 mins (auto)

Post randomisation contact – after 6 weeks (4 weekly thereafter)

Woman's Survey – 5-10 mins (auto)

End of pregnancy / birth

Maternal and neonatal outcomes (capturing outcomes up to primary discharge or 28 days post birth)

Stopping or switching treatment is a common part of usual clinical care. A woman can continue in the study (for collection of further data) after discontinuation / addition (s) to treatment.

CHANGE OF STUDY STATUS

- A **'change in study status'** form on REDCap should be completed for **all women** where you may not have all the information to complete the study outcome pages on REDCap

SERIOUS ADVERSE EVENTS

Please report the following as SAEs on REDCap within 24 hours of becoming aware:

- **Maternal death**
- **Maternal stroke**
- **Stillbirth after 24 weeks' gestation**
- **Neonatal death up to 28 days**