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A comparison of physiology-based interpretation of the fetal heart rate patterns during labour at term to guideline-based interpretation in the prediction of neonatal and labour outcomes

Submission date 20/12/2025	**Recruitment status** Recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 14/01/2026	**Overall study status** Ongoing	
Last Edited 12/01/2026	**Condition category** Pregnancy and Childbirth	

Plain English summary of protocol
Not provided at time of registration

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Study information

Scientific Title
Physiology-based versus guideline-based interpretation of intrapartum cardiotocograph in nulliparous women in term labour at baseline and longitudinally in the prediction of early neonatal outcome: a prospective observational study with randomisation of interpretation methods

Acronym
PHYSGUIDE

Study objectives
The study compares Physiology-based CTG interpretation to Guidelines-based CTG interpretation in the prediction of a composite adverse perinatal outcome including; 5-minute Apgar score <7, neonatal acidosis defined as pH <7.05 and base excess <-12mmol/l, antenatal brain injury, admission to neonatal intensive care unit (NICU), neonatal encephalopathy, need for therapeutic cooling, neonatal sepsis, meconium aspiration syndrome, hypoglycaemia, feto-maternal haemorrhage, perinatal stroke, intrapartum or neonatal death <28 days. A secondary aim is to compare the incidence of emergency Caesarean section and instrumental vaginal delivery between the two methods of CTG interpretation.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 08/07/2025, Comitato Etico Territoriale Area Centro-EST Veneto (Comitato Etico Territoriale, Area Centro-Est Veneto, Azienda Ospedale Università Padova,Via Giustiniani 1, Padova, 35128, Italy; +39 498212341; ce.sperimentazione@aopd.veneto.it), ref: 6259/AT/25

Primary study design
Observational

Secondary study design
Cohort study

Study type(s)

Health condition(s) or problem(s) studied
Fetal heart rate patterns during labour at term

Interventions

This is a prospective observational study of Physiology-based interpretation of intrapartum CTG compared to Guidelines-based interpretation in the prediction of early neonatal outcome. Following enrolment, the site study coordinator informs the statistician and sends him the anonymised intrapartum CTG trace for assignment of a study number and randomisation to either Group A (Guideline-based interpretation/scoring first) or Group B (Physiology-based interpretation/scoring performed first). The site study coordinator enters the maternal characteristics, labour, and neonatal outcomes into the study database, which is overseen by the statistician. The statistician sends the randomised and anonymised CTG to the scorers who are blinded to the maternal characteristics, labour, and neonatal outcomes, for interpretation /scoring using standardised Physiology-based and Guideline-based tools. The timing of the (alternative) interpretation of the same CTG is randomly allocated to either 15 weeks or 20 weeks after the first interpretation, with a different but linked number also blinded to the scorers, so that no CTG can be identified by the scorers or interpreted/scored using both methods within 3 months of the first scoring.

The women and babies are monitored with continuous CTG as clinically indicated and managed according to the local clinical protocols and practice. The maternal demographics, labour characteristics, and neonatal outcomes entered into the study database by the centre study coordinator is reviewed by the statistician for consistency and accuracy of data entry. The scorers send the CTG scores to the statistician for entry into the study database and subsequent analyses of perinatal and neonatal outcomes at baseline 0 - 2 hours, and longitudinally 2 - 8 hours, and 1 hour before birth.

Intervention Type
Other

Primary outcome(s)
1. The primary outcome is a composite of adverse perinatal outcomes, including: 5-minute Apgar score, neonatal acidosis defined as pH <-12mmol/l, admission to neonatal intensive care unit (NICU), incidence of neonatal encephalopathy, need for therapeutic cooling, meconium aspiration syndrome, persistent hypoglycaemia, perinatal stroke (MRI diagnosis), feto-maternal haemorrhage (low haemoglobin), or intrapartum or neonatal death measured using a review of patient notes at one time point

Key secondary outcome(s))
1. Incidence of emergency Caesarean section and instrumental vaginal delivery measured using a review of patient notes at one time point

Completion date
18/11/2028

Eligibility

Key inclusion criteria
1. Primigravid/Nulliparous women admitted in term labour (defined as uterine contractions frequency of 1 or more in 10 minutes and/or cervical dilatation >/=3cm after 37 completed weeks of gestation)
2. Managed with continuous CTG monitoring
3. Consent to participate in the study

Healthy volunteers allowed

Yes

Age group
Adult

Lower age limit
18 years

Upper age limit
50 years

Sex
Female

Total final enrolment
0

Key exclusion criteria
1. Parous women
2. Women with non-cephalic fetal presentation
3. Fetal abnormality
4. Multiple pregnancy
5. Antenatal CTG recording (defined as no uterine contractions and no cervical dilatation)
6. Abnormal CTG recording (without uterine contractions or cervical dilatation >/=3cm)

Date of first enrolment
18/11/2025

Date of final enrolment
17/11/2028

Locations

Countries of recruitment
Italy

Sponsor information

Organisation
University of Ferrara

ROR
https://ror.org/041zkgm14

Funder(s)

Funder type

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			12/01/2026	No	Yes