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Partogram Action Line Study (PALS2)

Submission date
06/07/2005

Recruitment status
No longer recruiting

Registration date
24/08/2005

Overall study status
Completed

Last Edited
27/11/2015

Condition category
Pregnancy and Childbirth

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
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Liverpool Women's Hospital
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Liverpool
United Kingdom
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
LWH0147

Study information

Scientific Title

Partogram Action Line Study (PALS2)

Acronym
PALS 2

Study objectives
To assess the effect of managing labour using two different partograms on maternal satisfaction and caesarean section rate

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

Participant information sheet

Health condition(s) or problem(s) studied
Management of labour progress

Interventions
2 or 4 hour partogram

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Overall caesarean section rate, maternal dissatisfaction (score <15)

Secondary outcome measures
Maternal: duration of labour (randomisation-delivery interval), use of oxytocin for augmentation, postpartum haemorrhage (PPH) (>500 ml), use of analgesia, number of vaginal

examinations, vaginal operative delivery rate.
Neonatal: Admission to Special Care Baby Unit (SCBU), APGAR scores (Appearance, Pulse, Grimace, Activity, Respiration) <7 at 5 min, neonatal seizures, birth asphyxia (defined as cord pH ≤7, base excess ≥12.0 mmo/l)

Overall study start date
01/09/1998

Completion date
31/08/2005

Eligibility

Key inclusion criteria
1. Gestational age >37 weeks
2. Primigravidae
3. Spontaneous labour defined as:
a. Cervix is either partically or fully effaced and >3 cm dilated
b. Regular uterine contractions are present (at least two in ten minutes >30 seconds)
4. Live baby
5. Singleton
6. Cephalic
7. Satisfactory admission cardiotocogram (CTG)

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
3000

Key exclusion criteria
1. Multigravidae
2. Insulin dependent diabetics
3. Significant fetal malformations
4. Contraindications to use of oxytocin

Date of first enrolment
01/09/1998

Date of final enrolment
31/08/2005

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Liverpool Women's Hospital
Liverpool Women's NHS Foundation Trust
Midwifery Research Dept
Crown Street
Liverpool
United Kingdom
L8 7SS

Sponsor information

Organisation
Liverpool Women's Hospital (UK)

Sponsor details
Crown Street
Liverpool
England
United Kingdom
L8 7SS

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/00eysw063

Funder(s)

Funder type
Government

Funder Name
Liverpool Women's Hospital NHS R&D Support Funding

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/08/2006		Yes	No