ISRCTN78346801 https://doi.org/10.1186/ISRCTN78346801

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
Prof Tina Lavender

Contact details
Midwifery Research Dept
Liverpool Women's Hospital
Crown Street
Liverpool
United Kingdom
L8 7SS

Additional identifiers

Protocol serial number
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

Study type(s)
Not Specified

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(s)
Overall caesarean section rate, maternal dissatisfaction (score <15)

Key secondary outcome(s))
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)

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

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

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
United Kingdom

England

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)

ROR
https://ror.org/00eysw063

Funder(s)

Funder type
Government

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

Results and Publications

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