

Partogram Action Line Study (PALS2)

Submission date 06/07/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 24/08/2005	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 27/11/2015	Condition category Pregnancy and Childbirth	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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

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United Kingdom
L8 7SS

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 mmol/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 partially 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