

Fetal scalp blood pH or lactate determination in the management of intrapartum fetal distress: A randomised controlled multi-centre trial

Submission date

23/09/2007

Recruitment status

No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date

02/10/2007

Overall study status

Completed

☐ Statistical analysis plan

☒ Results

Last Edited

03/06/2008

Condition category

Pregnancy and Childbirth

☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

Study objectives

The analysis of fetal scalp blood pH has been the gold standard in intrapartum management of suspected or known pathological fetal heart rate traces. However, this method has a reported sampling failure rate of 11-21%. Lactate analysis has simplified sampling, mainly due to the minimal amount of blood needed. Lactate is also an end product after anaerobic metabolism, which is of interest to analysis. Our hypothesis is that analysis of lactate in fetal scalp blood is at least as good as pH determination in the prevention of severe acidemia at birth with less sampling failure.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Karolinska Institute Regional Ethics Committee. Approved in 2002 (ref: 109/02).

Study design

Randomised controlled trial.

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Prevention

Participant information sheet

Health condition(s) or problem(s) studied

Intrapartum fetal monitoring

Interventions

Of the 3,007 participants recruited and randomised, 15 participants were excluded due to multiple pregnancies or gestational age <34 weeks. Final analysis was carried out on 2,992 cases, 1,496 in each arm.

Oral and written information about the trial was given to possible participants at the antenatal clinic in late pregnancy. Oral consent was obtained from the participants at antenatal follow up visits or in early labour. Randomisation of participants to the two arms was performed at the time a clinician decided to perform a fetal scalp blood analysis.

Interventions: Fetal scalp blood analysis for pH or lactate as basis for decision to intervene (cesarean section or instrumental delivery) or not.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Prevalence of metabolic acidemia or pH less than 7.00

Secondary outcome measures

Secondary outcome measures:

1. Protocol violation (mainly due to failed sampling or analysis)
2. Rate of instrumental deliveries
3. Rate of cesarean section
4. Apgar score less than 7 at 5 min
5. Admissions to neonatal intensive care unit

Tertiary outcome measures:

1. Prevalence of pH less than 7.10
2. Rate of intervention due to fetal distress
3. Rate of Hypoxic Ischemic Encephalopathy (HIE)

Overall study start date

13/12/2002

Completion date

31/12/2005

Eligibility**Key inclusion criteria**

1. Women in labour with a singleton pregnancy
2. Gestational age >34 weeks
3. Cephalic presentation
4. Clinical situation where a fetal scalp blood sampling was indicated
5. Those who had given consent

Participant type(s)

Patient

Age group

Adult

Sex

Female

Target number of participants

Initial target number: 3,000 (3,007 recruited)

Key exclusion criteria

1. Gestational age <34 weeks
2. Breech or multiple pregnancies

Date of first enrolment

13/12/2002

Date of final enrolment

31/12/2005

Locations

Countries of recruitment

Sweden

Study participating centre

Department of Obstetrics and Gynaecology

Stockholm

Sweden

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Sponsor information

Organisation

Karolinska University Hospital (c/o Lennart Nordström)

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Sponsor type

University/education

ROR

<https://ror.org/00m8d6786>

Funder(s)

Funder type

Research organisation

Funder Name

Signhild Engqvists Research Foundation (Signhild Engqvists Stiftelse) (Sweden)

Funder Name

The Stockholm Public Labour Ward Department Memorial Research Foundation (Allmänna BB's minnesfond) (Sweden)

Funder Name

The Regional City Council Research and Development Foundations (Sweden)

Funder Name

The Health and Medical Committee of the Region Västra Götland (Sweden)

Funder Name

Medexa AB (Sweden)

Funder Name

Lomma (Sweden)

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	07/06/2008		Yes	No