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Extending Midwife/nurse Roles in the routine Examination of the Newborn: randomised controlled evaluation and cost-effectiveness (EMREN trial)

Submission date
25/04/2003

Recruitment status
No longer recruiting

Registration date
25/04/2003

Overall study status
Completed

Last Edited
08/11/2022

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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
HTA 94/40/05

Study information

Scientific Title
Extending Midwife/nurse Roles in the routine Examination of the Newborn: randomised controlled evaluation and cost-effectiveness (EMREN trial)

Acronym
EMREN

Study objectives
The project will evaluate the cost effectiveness of extending midwifery practice in the routine examination of the newborn. The main study is an RCT, with 1000 babies in each arm, of outcome and cost effectiveness of examination by trained junior doctors compared with examination by trained midwives. The value of a further examination at ten days will also be assessed. In depth interviews will be held with paediatricians, midwives, GPs, nurses, patients and Royal Colleges. Effects on the NHS labour market and training needs will be analysed. The research addressed general and specific issues of extending nursing and midwifery roles, concerns regarding junior doctor hours and the timing of examinations of newborn babies, and will inform NHS policy.

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
Childbirth

Interventions

1. Neonatal examination by trained junior doctors
2. Neonatal examination by trained mid-wives

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Referrals assessed as appropriate and as major or minor by three independent consultants. Problems identified during the first year of life assessed as identifiable at 24 hours. Quality assessment by video against an agreed written proforma. Maternal satisfaction. Opinion of professionals and mothers about aspects of the examination.

Secondary outcome measures
Not provided at time of registration.

Overall study start date
01/03/1999

Completion date
31/08/2001

Eligibility

Key inclusion criteria
Newborn infants

Participant type(s)
Patient

Age group
Neonate

Sex
Not Specified

Target number of participants
2000

Key exclusion criteria
Not provided at time of registration.

Date of first enrolment
01/03/1999

Date of final enrolment
31/08/2001

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
The Public & Environmental Health Research Unit (PEHRU)
London
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Sponsor information

Organisation
Department of Health (UK)

Sponsor details
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Sponsor type
Government

Website
http://www.dh.gov.uk/en/index.htm

ROR
https://ror.org/03sbpja79

Funder(s)

Funder type
Government

Funder Name

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan
Not provided at time of registration

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	HTA monograph	01/04/2004		Yes	No