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Home or in-hospital cervical ripening for induction of labour

Submission date
03/07/2020

Recruitment status
No longer recruiting

Registration date
10/07/2020

Overall study status
Completed

Last Edited
05/08/2025

Condition category
Pregnancy and Childbirth

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

Plain English summary of protocol

Background and study aims
Induction of labour (IOL) is the most common obstetric intervention offered to women when the risks of continuing the pregnancy are thought to outweigh the risks of delivery. Increases in IOL rates mean that 30.6% of pregnant women in the UK have their labour induced. Cervical ripening is a key component of IOL, where a drug or mechanical method applied over a number of hours causes softening, shortening, and opening of the cervix in preparation for labour. Traditionally cervical ripening has been performed entirely in-hospital to allow monitoring of maternal/fetal wellbeing and recognition of complications. However, an increasing number of maternity units offer home cervical ripening, where women attend hospital for initial assessment and administration of the cervical ripening agent and then return home (to her own home, or that of a friend/relative/birth partner) for a period of time (usually 24 hours), before reassessment in hospital. Home cervical ripening has the potential to reduce hospital stay during IOL, reducing costs to health services. However, the safety and acceptability of home cervical ripening have not been fully evaluated. Potential NHS cost savings could be offset by increased costs of any additional illness resulting from home cervical ripening, costs to parents may be increased, and the acceptability of home cervical ripening is unknown. Health services need to balance the full resource impact of IOL with the need to provide safe and acceptable care. The aim of this study is to find out whether it is safe, effective, cost-effective and acceptable to women to carry out home cervical ripening during IOL.

Who can participate?
Women with single pregnancies having IOL at or beyond 39 weeks gestation

What does the study involve?
This study will use anonymised routinely collected health data from electronic maternity records systems. Patients will also be asked to complete an online survey, and a smaller group of these patients will be asked if they would like to be interviewed by the researcher.

What are the possible benefits and risks of participating?
Patients will be able to opt out if they do not want their data to be included in the study. As such there are no direct risks of taking part. It is possible that for some women, answering questions may bring back stressful or emotional memories. However, the questionnaire is comprised of

questionnaires that have been frequently used and found to be acceptable in similar populations, and interviews with women and their partners will be undertaken by experienced research staff who will be sensitive to participants who appear to be distressed.

Where is the study run from?
University of Edinburgh (Edinburgh Clinical Trials Unit), University of Stirling and City, University of London (UK)

When is the study starting and how long is it expected to run for?
December 2019 to June 2022

Who is funding the study?
National Institute for Health Research Health Technology Assessment (NIHR HTA) (UK)

Who is the main contact?
CHOICE.Study@ed.ac.uk

Study website
https://www.ed.ac.uk/usher/edinburgh-clinical-trials/our-studies/ukcrc-studies/choice

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
276788

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
AC20020, HTA - NIHR127569, IRAS 276788

Study information

Scientific Title
Cervical Ripening at Home or In-Hospital - prospective cohort study and process evaluation (CHOICE study)

Acronym
CHOICE

Study objectives
The aim is to compare home versus in-hospital cervical ripening to determine whether home cervical ripening is within an acceptable margin of in-hospital cervical ripening for the safety outcome of neonatal unit (NNU) admission, whether it is more acceptable to women and whether it is cost-effective from both NHS and patient perspectives.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 17/06/2020, York & Humber – Sheffield Research Ethics Committee (NHSBT Newcastle Blood Donor Centre, Holland Drive, Newcastle upon Tyne, NE2 4NQ, UK; +44 (0)207 1048084; sheffield.rec@hra.nhs.uk), ref: 20/YH/0145

Study design
Prospective multicentre observational cohort study, with internal pilot phase, using data obtained from hospital electronic health records, a cost-effectiveness analysis, and a questionnaire-based survey and nested case studies evaluating process and women/partner experiences

Primary study design
Observational

Secondary study design
Nested process evaluation study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Women with singleton pregnancies having induction of labour at or beyond 39 weeks gestation

Interventions

Observational cohort:
The researchers will include at least 14 maternity units offering only in-hospital cervical ripening and at least 12 offering dinoprostone home cervical ripening. They will concurrently collect data from at least four maternity units offering balloon catheter home cervical ripening to allow initial exploratory comparison of these two different methods of cervical ripening. To achieve a sufficiently sized cohort for analysis (taking into account the need for statistical techniques to reduce biases inherent in observational studies) and maximise the value and generalisability of the study, the researchers will collect data from a large and broad cohort of women having IOL.

Women will be informed about the study through a variety of methods including posters in participating sites, information leaflets, online adverts on hospital/maternity websites and relevant social media sites, and information in maternal electronic maternity records (for women who can access their own maternity record). Women will be able to opt out of the study by informing their midwife or by emailing an independent study contact. Details of how to opt out will be included in the study materials.

De-identified data will be extracted from the BadgerNet Maternity system data on all eligible women having IOL, from multiple existing data fields, supplemented by new bespoke, data entry fields enabled in participating sites. Data from women who have opted out will not be included in the extraction. All data will be securely transferred to the CHOICE database for analysis. Linked NNU admission data will be obtained from the National Neonatal Research Database.

The researchers propose a pilot phase to determine the parameters of the primary outcome and achievability of obtaining the required sample size for analysis. They will perform an analysis after 6 months of recruitment (evaluable target 600 women in each arm), and will assess variation of the primary outcome at the pilot stage; along with that of other measures of neonatal morbidity included as secondary outcomes.

Analysis of data for outcome measures will be performed by the trial statistician.

qCHOICE
A process evaluation seeks to understand and explain the ways in which interventions such as cervical ripening are implemented, and how they work in different contexts. The context in which an intervention is implemented (e.g geography, socio-economics and work culture) is a major factor impacting on outcomes both planned and unplanned. Therefore it is important to study how cervical ripening is being undertaken, and its impact on psychosocial and economic outcomes in different contexts.

To do this the researchers will use a survey and multiple case study design. Both qualitative and quantitative data will be collected - specifically, a questionnaire, semi-structured interviews with women and birth partners, audio recordings of clinician/women consultations, interviews and focus-group discussions with professionals and service managers/commissioners.

The questionnaire will be administered in at least 12 sites particpating in the observational cohort study. The survey will involve women who have experienced labour induction. It will assess differences between setting +/- method of cervical ripening in terms of women's satisfaction, experience, and psychosocial outcomes. A consecutive sample of women who had any form of IOL involving cervical ripening will be invited to complete the survey online or by post around 4-6 weeks postnatally. The questionnaire will comprise validated tools plus a small number of questions relating to service user costs, some information about their IOL and will ask

women to indicate their willingness to be contacted for a subsequent interview (case study sites only).

Case studies will be performed in five of the observational cohort study sites: two in Scotland and three in England. The case study sites will be maternity services. We will select sites that vary by size (i.e. annual births), by policy for cervical ripening (home or hospital) and by sociodemographic and geographical characteristics.

Within each site the researchers will undertake semi-structured interviews to assess the acceptability of home CR to women, their families and other key stakeholders, explore women and partners lived experience of CR (home or hospital) IOL and subsequent labour and assess the local pathways and processes involved in decision making about home/hospital CR, identifying barriers and enablers in different contexts. Individual interviews with stakeholders and senior professionals will be semistructured, conducted face-to-face, skype or by telephone and audio-recorded.

To provide a more in-depth understanding of the acceptability of home cervical ripening, and of the discussion and decision-making processes involved in potentially offering home cervical ripening to women we will audio record a sample of antenatal consultations between obstetricians or midwives and women/partners in which IOL will be discussed.

The process evaluation component of the study will also collect key data for the economic evaluation; namely, costs incurred by women in relation to IOL, for all modes but with a particular focus on home CR.

These will be collected through the inclusion of costing questions in the women's postnatal survey and more in-depth discussion in interviews, in order to enhance interpretation.

Intervention Type
Other

Primary outcome measure
Observational study:
Admission to neonatal unit (NNU) within 48 hours, for a period of 48 hours or more, measured using patient records at a single timepoint

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Sense of control (agentry) in labour, based on the use of the labour agentry scale which will form part of the patient questionnaire at a single timepoint

Secondary outcome measures
Measured using patient records at a single timepoint:
1. Neonatal morbidities
2. Maternal morbidities
3. Mode of birth
4. Time of birth
5. Duration of hospital stay
5. Breastfeeding

Health economic outcomes will form part of the patient questionnaire, and will be measured by patient-related resource use and expenditures of cervical ripening for women

Overall study start date
01/12/2019

Completion date
30/06/2022

Eligibility

Key inclusion criteria
Current inclusion criteria as of 17/11/2022:
Observational study:
For data collection:
1. Gestation 37+0 weeks or more
2. Undergoing IOL
For primary analysis:
1. Gestation of 39+0 weeks or more

Qualitative study:
For questionnaire-based survey:
1. Gestation 37+0 weeks or more
2. Undergoing IOL
For case studies:
1. Gestation of 37+0 weeks or more

Previous inclusion criteria:
Observational study:
For data collection:
1. Gestation 37+0 weeks or more
2. Undergoing IOL
For primary analysis:
1. Gestation of 39+0 weeks or more

Qualitative study:
For questionnaire-based survey:
1. Gestation 39+0 weeks or more
2. Undergoing IOL
For case studies:
1. Gestation of 39+0 weeks or more

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
Observational study: The primary analysis sample size is 8,533 women with uncomplicated pregnancies at 39 weeks or more undergoing IOL. To achieve this, and to put our findings into

context, we will collect data on a much broader cohort of around 41,000 women having IOL after 37 weeks. Qualitative study: The sample size required to compare the experiences of women who had home and hospital cervical ripening is estimated to be 89 per group (178 in total). The sample sizes for the case studies, interviews, focus groups and recordings of visits are pragmatic and based on an estimation of numbers needed in a purposive sample to achieve data saturation.

Total final enrolment
25677

Key exclusion criteria
Current exclusion criteria as of 17/11/2022:
Observational study:
For data collection:
1. Opted out of data provision (checkbox)
Applied for primary analysis:
1. Grand multiparity (6 or more previous pregnancies)
2. Previous caesarean section
3. Antepartum stillbirth (before cervical ripening initiated)
4. Class III obesity at booking (BMI 40 kg/m2 or more)
5. Prelabour rupture of membranes documented as primary or other indication for IOL (prolonged ROM; SROM; ?SROM)
6. Maternal, fetal or medical condition that would/could preclude home cervical ripening documented as primary or other indication for IOL
7. Maternal conditions: proteinuria; hypertension; antepartum haemorrhage; diabetes; obstetric cholestasis; past obstetric history; pre-eclampsia; PIH/PET (not defined); PIH; PET; thrombophilia
8. Fetal conditions: oligohydramnios; reduced liquor volume; macrosomia; intrauterine growth restriction (IUGR); static growth; congenital fetal anomaly; polyhydramnios; abnormal CTG /Doppler; breech; reduced fetal movements; termination of pregnancy for fetal anomaly

Qualitative study:
For case studies:
1. Women who did not have IOL at 37+0 weeks of gestation
2. Women who had IOL for medical reasons
3. Women who had an elective cesarean section
4. Women who have experienced intrauterine death, stillbirth or neonatal death

Previous exclusion criteria:
Observational study:
For data collection:
1. Opted out of data provision (checkbox)
Applied for primary analysis:
1. Grand multiparity (6 or more previous pregnancies)
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Date of first enrolment
28/09/2020

Date of final enrolment
30/06/2022

Locations

Countries of recruitment
England

Scotland

United Kingdom

Study participating centre
Aberdeen Maternity Hospital
Foresterhill
Aberdeen
United Kingdom
AB25 2ZL

Study participating centre
NHS Borders
Newstead
Melrose
United Kingdom
TD6 9DB

Study participating centre
NHS Fife
Hayfield House
Hayfield Road
Kirkcaldy

United Kingdom
KY2 5AH

Study participating centre
NHS Highland
Reay House
17 Old Edinburgh Road
Inverness
United Kingdom
IV2 3HG

Study participating centre
NHS Lanarkshire
14 Beckford Street
Hamilton
United Kingdom
ML3 0TA

Study participating centre
NHS Tayside
Kings Croos
Clepington Road
Dundee
United Kingdom
DD3 8EA

Study participating centre
Ashford and St Peter's Hospitals NHS Foundation Trust
St Peters Hospital
Guildford Road
Chertsey
United Kingdom
KT16 0PZ

Study participating centre
Birmingham Women's NHS Foundation Trust
Birmingham Womens Hospital
Metchley Park Road
Birmingham
United Kingdom
B15 2TG

Study participating centre
Dorset County Hospital NHS Foundation Trust
Dorset County Hospital
Williams Avenue
Dorchester
United Kingdom
DT1 2JY

Study participating centre
County Durham and Darlington NHS Foundation Trust
Darlington Memorial Hospital
Hollyhurst Road
Darlington
United Kingdom
DL3 6HX

Study participating centre
Epsom and St Helier University Hospitals NHS Trust
St Helier Hospital
Wrythe Lane
Carshalton
United Kingdom
SM5 1AA

Study participating centre
Gateshead Health NHS Foundation Trust
Queen Elizabeth Hospital
Sheriff Hill
Gateshead
United Kingdom
NE9 6SX

Study participating centre
Wye Valley NHS Trust
County Hospital
27 Union Walk
Hereford
United Kingdom
HR1 2ER

Study participating centre
King's College Hospital NHS Foundation Trust
Kings College Hospital
Denmark Hill
London
United Kingdom
SE5 9RS

Study participating centre
The Queen Elizabeth Hospital, King's Lynn, NHS Foundation Trust
Queen Elizabeth Hospital
Gayton Road
King's Lynn
United Kingdom
PE30 4ET

Study participating centre
Lancashire Teaching Hospitals NHS Foundation Trust
Royal Preston Hospital
Sharoe Green Lane
Fulwood
Preston
United Kingdom
PR2 9HT

Study participating centre
North Cumbria Integrated Care NHS Foundation Trust
Pillars Building
Cumberland Infirmary
Infirmary Street
Carlisle
United Kingdom
CA2 7HY

Study participating centre
Walsall Healthcare NHS Trust
Manor Hospital
Moat Road
Walsall
United Kingdom
WS2 9PS

Study participating centre
South Warwickshire University NHS Foundation Trust
Warwick Hospital
Lakin Road
Warwick
United Kingdom
CV34 5BW

Study participating centre
The Royal Wolverhampton NHS Trust
New Cross Hospital
Wolverhampton Road
Heath Town
Wolverhampton
United Kingdom
WV10 0QP

Study participating centre
Worcestershire Acute Hospitals NHS Trust
Worcestershire Royal Hospital
Charles Hastings Way
Worcester
United Kingdom
WR5 1DD

Sponsor information

Organisation
University of Edinburgh

Sponsor details
Research & Development Management Suite
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United Kingdom
EH16 4TJ
+44 (0)1312426226
Jo-Anne.Robertson@ed.ac.uk

Sponsor type

University/education

Website
http://www.ed.ac.uk/home

ROR
https://ror.org/01nrxwf90

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
28/02/2024

Individual participant data (IPD) sharing plan
Individual patient-level data will not be shared but once the final analyses are complete, permission to share an anonymised version of the final analysis dataset will be sought.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?

Protocol article	04/05/2021	06/05/2021	Yes	No
HRA research summary		28/06/2023	No	No
Results article	01/12/2024	17/01/2025	Yes	No