

# Home or in-hospital cervical ripening for induction of labour

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<b>Registration date</b> 10/07/2020	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 05/08/2025	<b>Condition category</b> Pregnancy and Childbirth	<input type="checkbox"/> 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

## Contact information

**Type(s)**

Scientific

**Contact name**

Dr Sarah Stock

**ORCID ID**

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**Contact details**

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+44 (0)131 242 6449  
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## Additional identifiers

**Clinical Trials Information System (CTIS)**

Nil known

**Integrated Research Application System (IRAS)**

276788

**Protocol serial number**

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

## **Study type(s)**

Treatment

## **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 (evaluative 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.

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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 participating 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(s)**

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

## **Key secondary outcome(s)**

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

## **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

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Sex**

Female

### **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/m<sup>2</sup> 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**

United Kingdom

England

Scotland

**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  
Cleington 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

**ROR**  
<https://ror.org/01nrxf90>

## Funder(s)

**Funder type**  
Government

**Funder Name**  
Health Technology Assessment Programme

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

**Funding Body Type**  
Government organisation

**Funding Body Subtype**  
National government

**Location**  
United Kingdom

# Results and Publications

## 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?
<a href="#">Results article</a>		01/12/2024	17/01/2025	Yes	No
<a href="#">Protocol article</a>		04/05/2021	06/05/2021	Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes