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Induction of labour for predicted macrosomia: the Big Baby trial

Submission date
04/04/2018

Recruitment status
No longer recruiting

Registration date
12/04/2018

Overall study status
Completed

Last Edited
09/07/2025

Condition category
Pregnancy and Childbirth

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

Plain English summary of protocol

Background and study aims
Difficulty in delivering the shoulders of a baby after the head has been delivered can be a serious complication during birth. Most babies that get into such trouble are larger than average. It has been suggested that if we can predict by ultrasound scan in the last weeks of pregnancy which babies are large and at increased risk, then we could deliver them a week or so earlier and reduce the chance of such complications. However, the available evidence is not clear, and can be interpreted in different ways. The aim of this study is to find out whether delivering large babies earlier is the right thing to do for baby and mother.

Who can participate?
Pregnant women aged 18 years or over where an ultrasound scan suggests that the baby in the womb is larger than expected for the woman's size, therefore potentially at risk of problems with delivery of the shoulders during birth

What does the study involve?
Participants are randomly allocated to either an early induction of labour, with the aim to start labour at 38 weeks, or a control group where care is as normal and labour is left to start naturally. The study looks at whether, as a result of earlier birth, there are fewer instances of complications such as difficulty with the delivery of the shoulders.

What are the possible benefits and risks of participating?
The study will help decide what the safest method is to care for pregnancies where, because of the large size of the baby, complications may occur during labour.

Where is the study run from?
Warwick Clinical Trials Unit (UK)

When is the study starting and how long is it expected to run for?
January 2018 to May 2023

Who is funding the study?
National Institute for Health Research - HTA (UK)

Who is the main contact?
Amy Arnold, BigBaby@warwick.ac.uk, Bigbaby2Up@warwick.ac.uk

Study website
http://warwick.ac.uk/bigbaby

Contact information

Type(s)
Scientific

Contact name
Ms Amy Arnold

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Warwick Medical School
Gibbet Hill Campus
University of Warwick
Coventry
United Kingdom
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+44 (0)24 76 151825
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Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
229163

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 36723, IRAS 229163, NIHR Evaluation, Trials and Studies Co-ordinating Centre (NETSCC) Grant Codes: 16/77/02

Study information

Scientific Title
Induction of labour for predicted macrosomia: the Big Baby trial

Acronym
Big Baby

Study objectives
Difficulty in delivering the shoulders of a baby after the head has been delivered can be a serious complication during birth. Most babies that get into such trouble are larger than average. It has been suggested that if we can predict by ultrasound scan in the last weeks of pregnancy which babies are large and at increased risk, then we could deliver them a week or so earlier and reduce the chance of such complications.

However, the available evidence is not clear, and can be interpreted in different ways. To know if delivering large babies earlier is the right thing to do for baby and mother an objective clinical trial is needed to see whether it is really of benefit. The trialists propose to do this through a study of 4000 pregnancies where an ultrasound scan had suggested that the baby in the womb is larger than expected for the woman's size, therefore potentially at risk of problems with delivery of the shoulders during birth. The study will help decide what the safest method is to care for pregnancies where, because of the large size of the baby, complications may occur during labour.

Ethics approval required
Old ethics approval format

Ethics approval(s)
South West-Exeter Research Ethics Committee, 19/03/2018, ref: 18/SW/0039

Study design
Randomized; Both; Design type: Treatment, Other

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)

Treatment

Participant information sheet
Will be available at: http://warwick.ac.uk/bigbaby

Health condition(s) or problem(s) studied
Maternal care for suspected macrosomia

Interventions
Current interventions as of 29/06/2023:
Big Baby
With the mother's consent, she would be allocated at random (telephone or computer-based randomisation) into either an early induction of labour group, with the aim to start labour at 38 weeks, or a control group where care is as normal and onset labour is awaited to start naturally. The trialists will then look at whether, as a result of earlier birth, there were fewer instances of complications such as difficulty with the delivery of the shoulders. Follow-up is 6 months.

Big Baby 2Up
As the Big Baby Trial was getting underway, evidence emerged linking reduced cognitive, reading and language skills and slightly increased learning problems in babies born one or two weeks from full term, but it is not known whether this effect is due to those born small for gestation or also applies to big babies in the same way. In this sub-study, we will assess the cognitive and language function of babies born to women participating in The Big Baby Trial when they reach 24 months of age. This will be assessed via the PARCA-R (Parent Report of Children's Abilities-Revised) questionnaire (https://www2.le.ac.uk/partnership/parca-r/parca-r-resources).

Pregnant women, their partners, midwives and obstetricians must have evidence-based information to be able to discuss and make informed decisions about the timing of birth if their baby is predicted to be above the 90th centile on the fetal growth chart and balance the risk of stillbirth, shoulder dystocia, maternal and neonatal morbidity, and babies longer-term cognitive function.

Primary research question
In babies with suspected macrosomia antenatally, does near-term delivery affect non-verbal cognition and language development, as measured by the Parent Report of Children's Ability-Revised (PARCA-R), at 24 months?

Secondary research questions
1. In infants with suspected macrosomia does induction at 38+0 - 38+4 weeks, when compared to expectant management, affect cognitive function (non-verbal cognition; language development) at 24 months?
2. In babies with suspected macrosomia does gestational age at the time of birth, weight centile, mode of delivery (normal vaginal delivery, assisted delivery, caesarean section (elective / emergency)) and exclusive breastfeeding predict cognitive function at 24 months?
3. What are the costs and health consequences of near-term delivery in macrosomic babies?

Previous interventions:
With the mother's consent, she would be allocated at random (telephone or computer-based randomisation) into either an early induction of labour group, with the aim to start labour at 38 weeks, or a control group where care is as normal and onset labour is awaited to start naturally.

The trialists will then look at whether, as a result of earlier birth, there were fewer instances of complications such as difficulty with the delivery of the shoulders. Follow-up is 6 months.

Intervention Type
Other

Primary outcome measure
Current primary outcome measure as of 29/06/2023:
Big Baby
Incidence of shoulder dystocia, definition by the Royal College of Obstetricians and Gynaecologists as, 'a vaginalcephalic delivery that requires additional obstetric manoeuvres to deliver the fetus after the head has delivered and gentle traction has failed'. Shoulder dystocia will be confirmed by a notes review, undertaken by an independent expert panel; data on management of shoulder dystocia and its potential complications are an important performance metric for maternity units and will be recorded reliably in the notes; Timepoint(s): End of the study

Big Baby 2Up
Non-verbal cognition and language development measured using the Parent Report of Children' s Ability-Revised (PARCA-R) at 24 months

Previous primary outcome measure:
Incidence of shoulder dystocia, definition by the Royal College of Obstetricians and Gynaecologists as, 'a vaginalcephalic delivery that requires additional obstetric manoeuvres to deliver the fetus after the head has delivered and gentle traction has failed'. Shoulder dystocia will be confirmed by a notes review, undertaken by an independent expert panel; data on management of shoulder dystocia and its potential complications are an important performance metric for maternity units and will be recorded reliably in the notes; Timepoint(s): End of the study

Secondary outcome measures
Current secondary outcome measure as of 29/06/2023:
Big Baby
Fetal outcomes:
Intrapartum:
1. Time recorded between delivery of the head and delivery of the body
2. Time in labour ward
3. Time from commencement of active second stage of labour until fetal expulsion
4. Stillbirths

Neonatal:
1. Neonatal death
2. Birth weight
3. Gestation at birth
4. Apgar score at five minutes
5. Fractures
6. Brachial plexus injuries
7. Admission to the neonatal unit/duration of stay
8. Hypoxic-ischaemic encephalopathy

9. Use of phototherapy
10. Respiratory morbidity
11. Hypoglycaemia

Infants:
1. Proportion under specialist medical care at 2 months for a problem related to intra-partum experience
2. Maternal report of infant health concerns at 6 months
3. In hospital health care costs

Maternal outcomes:
Intrapartum:
1. Duration of hospital stay prior to delivery
2. Mode of delivery
3. Perineal tear (episiotomy or spontaneous 1st to 4th degree perineal tear)
4. Vaginal/cervical laceration or tear
5. Primary postpartum haemorrhage (≥1000ml)
6. Retained placenta
7. Death

Post-partum:
1. Sepsis
2. Fever (>38.0°c)
3. Duration of hospital stay after delivery
4. Uptake of breastfeeding
5. Hospital readmission within 30 days of postnatal inpatient discharge

Longer term outcomes:
Women's physical and psychological health and satisfaction with delivery:
1. Experience; six simple questions (SSQ) at 2 months
2. Duration of exclusive breastfeeding at 2 and 6 months
3. Health-related quality of life (EQ-5D-5L) at baseline, 2 and 6 months (appropriate licences to allow reproduction of these questionnaires will be obtained)
4. Edinburgh post-natal depression scale at baseline, 2 and 6 months
5. Impact of Events Scale at 2 months
7. Post-partum bonding questionnaire at 2 months
8. Maternal report of infant health at 2 and 6 months
9. Urinary incontinence ICIQ-UI short form assessed at baseline, 2 and 6 months
10. Sexual function at baseline and 6 months
11. Maternal and infant death at 6 months from HES-ONS linked mortality data. Obtain if the 6 month follow-up is not completed
12. Participant health resource used for economic analysis for mother and baby at 2 and 6 months

Composite outcomes:
1. Intra-partum birth injury: one or both of fractures or brachial plexus injury
2. Prematurity associated problems: one or both of use of phototherapy or respiratory support
3. Maternal intra-partum complications: one or more of 3rd or 4th degree perineal tear, vaginal /cervical laceration or tear, or primary postpartum haemorrhage

Big Baby 2Up
1. Cognitive function (non-verbal cognition; language development) measured using the Parent

Report of Children's Ability-Revised (PARCA-R) at 24 months
2. Gestational age at the time of birth, weight centile, mode of delivery (normal vaginal delivery, assisted delivery, caesarean section (elective / emergency)) and exclusive breastfeeding as documented in patient medical records at 24 months
3. Cost and health consequences of near-term delivery will be measured by adapting our standardised resource use questionnaires which we have used successfully in our other trials at 24 months.

Previous secondary outcome measure:
Fetal outcomes:
Intrapartum:
1. Time recorded between delivery of the head and delivery of the body
2. Time in labour ward
3. Time from commencement of active second stage of labour until fetal expulsion
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Neonatal:
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Infants:
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Maternal outcomes:
Intrapartum:
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Post-partum:
1. Sepsis
2. Fever (>38.0°c)
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5. Hospital readmission within 30 days of postnatal inpatient discharge

Longer term outcomes:
Women's physical and psychological health and satisfaction with delivery:
1. Experience; six simple questions (SSQ) at 2 months
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2. Prematurity associated problems: one or both of use of phototherapy or respiratory support
3. Maternal intra-partum complications: one or more of 3rd or 4th degree perineal tear, vaginal /cervical laceration or tear, or primary postpartum haemorrhage

Overall study start date
01/01/2018

Completion date
26/05/2023

Eligibility

Key inclusion criteria
1. Women aged 18 years or over
2. Women with a fetus above 90th estimated fetal weight centile on ultrasound scan at 35+0 to 38+0 weeks gestation
3. Women with a cephalic presentation

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants

Planned Sample Size: 4000; UK Sample Size: 4000

Total final enrolment
2895

Key exclusion criteria
Current exclusion criteria as of 14/11/2018:
1. Multiple pregnancy
2. Breech pregnancy or transverse lie presentation
3. Induction of labour contra-indicated
4. Fetus with known serious abnormality
5. Home birth or elective caesarean section already planned
6. Caesarean section or induction indicated due to health conditions such as cardiac disease or hypertensive disorders
7. Women taking medications and insulin therapy for diabetes or gestational diabetes; women with these conditions who are not taking medication are eligible
8. Current diagnosis of major psychiatric disorder which requires antipsychotic medication
9. Women unable to give informed consent e.g. learning or communication difficulties that prevent understanding of the information provided
10. Prisoners
11. Previous stillbirth
12. Previous neonatal death ≤28 days
13. Current intrauterine fetal death

Previous exclusion criteria:
1. Multiple pregnancy
2. Breech pregnancy or transverse lie presentation
3. Induction of labour contra-indicated
4. Fetus with known serious abnormality
5. Home birth or elective caesarean section already planned
6. Caesarean section or induction indicated due to health conditions such as cardiac disease, epilepsy, or hypertensive disorders
7. Women taking medications and insulin therapy for diabetes or gestational diabetes; women with these conditions who are not taking medication are eligible
8. Current diagnosis of major psychiatric disorder which requires antipsychotic medication
9. Women unable to give informed consent e.g. learning or communication difficulties that prevent understanding of the information provided
10. Prisoners
11. Previous stillbirth
12. Previous neonatal death

Date of first enrolment
01/05/2018

Date of final enrolment
25/11/2022

Locations

Countries of recruitment
England

Scotland

United Kingdom

Wales

Study participating centre
University Hospital Coventry and Warwickshire
Clifford Bridge Road
Coventry
United Kingdom
CV2 2DX

Study participating centre
Shrewsbury and Telford Hospital NHS Trust
Mytton Oak Road
Shrewsbury
United Kingdom
SY3 8XQ

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

Study participating centre
Liverpool Women's Hospital NHS Foundation Trust
Crown St
Liverpool
United Kingdom
L8 7SS

Study participating centre
Heartland of England NHS Foundation Trust
Bordesley Green East
Birmingham
United Kingdom
B9 5SS

Study participating centre
George Eliot Hospital NHS Trust
College Street
Nuneaton
United Kingdom
CV10 7DJ

Study participating centre
The Pennine Acute Hospitals NHS Trust
Rochdale Road
Oldham
United Kingdom
OL1 2JH

Study participating centre
Royal Bolton Hospital
Bolton NHS Foundation Trust
Minerva Road
Farnworth
Bolton
United Kingdom
BL4 0JR

Study participating centre
Calderdale Royal Hospital
Woman's Service
Huddersfield Road
Halifax
United Kingdom
HX3 0PW

Study participating centre
Huddersfield Royal Infirmary
Woman's Service
Acre Street
Huddersfield
United Kingdom
HD3 3EA

Study participating centre
Darlington Memorial Hospital
Hollyhurst Road
Darlington
United Kingdom
DL3 6HX

Study participating centre
University Hospital of North Durham
North Road
Durham
United Kingdom
DH1 5TW

Study participating centre
Burnley General Hospital
Casterton Avenue
Burnley
United Kingdom
BB10 2PQ

Study participating centre
Royal Blackburn Hospital
Haslingden Road
Blackburn
United Kingdom
BB2 3HH

Study participating centre
Burnley General Hospital
Woman's Health - BGH
Casterton Avenue
Burnley
United Kingdom
BB10 2PQ

Study participating centre
Frimley Park Hospital
Portsmouth Road

Frimley
United Kingdom
GU16 7UJ

Study participating centre
Wexham Park Hospital
Wexham
Slough
United Kingdom
SL2 4HL

Study participating centre
Queen Charlotte's Hospital
Du Cane Road
London
United Kingdom
W12 0HS

Study participating centre
Leeds General Infirmary
Great George Street
Leeds
United Kingdom
LS1 3EX

Study participating centre
St James's Hospital
Beckett Street
Leeds
United Kingdom
LS9 7TF

Study participating centre
St Mary's Hospital
Oxford Road
Manchester
United Kingdom
M13 9WL

Study participating centre
Leighton Hospital
Leighton
Crewe
United Kingdom
CW1 4QJ

Study participating centre
Norfolk and Norwich University Hospital
Colney Lane
Colney
Norwich
United Kingdom
NR4 7UY

Study participating centre
University Hospital of North Tees
UH North Tees Obstetrics and Gynaecology
Hardwick Road
Stockton-On-Tees
Cleveland
United Kingdom
TS19 8PE

Study participating centre
Hinchingbrooke Hospital
Hinchingbrooke Park
Huntingdon
United Kingdom
PE29 6NT

Study participating centre
Peterborough City Hospital
Edith Cavell Campus
Bretton Gate
Bretton
Peterborough
United Kingdom
PE3 9GZ

Study participating centre

Salisbury District Hospital
Odstock Road
Salisbury
United Kingdom
SP2 8BJ

Study participating centre
Kings Mill Hospital
Mansfield Road
Sutton-In-Ashfield
United Kingdom
NG17 4JL

Study participating centre
Whiston Hospital
Warrington Road
Prescot
United Kingdom
L35 5DR

Study participating centre
Worcestershire Royal Hospital
Charles Hastings Way
Worcester
United Kingdom
WR5 1DD

Study participating centre
Ormskirk & District General Hospital
Wigan Road
Ormskirk
United Kingdom
L39 2AZ

Study participating centre
The Whittington Hospital
Highgate Hill
London
United Kingdom
N19 5NF

Study participating centre
Chelsea & Westminster Hospital
369 Fulham Road
London
United Kingdom
SW10 9NH

Study participating centre
West Middlesex University Hospital
Twickenham Road
Isleworth
United Kingdom
TW7 6AF

Study participating centre
Queen Elizabeth the Queen Mother Hospital
St Peter's Road
Margate
United Kingdom
CT9 4AN

Study participating centre
The Maidstone Hospital
Hermitage Lane
Maidstone
United Kingdom
ME16 9QQ

Study participating centre
Tunbridge Wells Hospital
The Tunbridge Wells Hospital
Tonbridge Road
Pembury
Tunbridge Wells
United Kingdom
TN2 4QJ

Study participating centre

Sunderland Royal Hospital
Kayll Road
Sunderland
United Kingdom
SR4 7TP

Study participating centre
South Tyneside District Hospital
Harton Lane
South Shields
United Kingdom
NE34 0PL

Study participating centre
Singleton Hospital
Sketty Lane
Sketty
Swansea
United Kingdom
SA2 8QA

Study participating centre
Neath Port Talbot Hospital
Baglan Way
Port Talbot
United Kingdom
SA12 7BX

Study participating centre
Royal Gwent Hospital
Cardiff Road
Newport
United Kingdom
NP20 2UB

Study participating centre
Nevill Hall Hospital
Abergavenny
United Kingdom
NP7 7EG

Study participating centre
York Hospital
Wigginton Road
York
United Kingdom
YO31 8HE

Study participating centre
Scarborough General Hospital
Woodlands Drive
Scarborough
United Kingdom
YO12 6QL

Study participating centre
Lister Hospital
Coreys Mill Lane
Stevenage
United Kingdom
SG1 4AB

Study participating centre
Luton & Dunstable Hospital
Lewsey Road
Luton
United Kingdom
LU4 0DZ

Study participating centre
Victoria Hospital (blackpool)
Whinney Heys Road
Blackpool
United Kingdom
FY3 8NR

Study participating centre
Hull Royal Infirmary
Anlaby Road
Hull

United Kingdom
HU3 2JZ

Study participating centre
Poole General Hospital
St Mary's Carpark
Longfleet Road
Poole
United Kingdom
BH15 2JB

Study participating centre
Musgrove Park Hospital (taunton)
Musgrove Park Hospital
Taunton
United Kingdom
TA1 5DA

Study participating centre
St Richard's Hospital
Spitalfield Lane
Chichester
United Kingdom
PO19 6SE

Study participating centre
Worthing Hospital
Lyndhurst Road
Worthing
United Kingdom
BN11 2DH

Study participating centre
Burton General Hospital
Burton Hospitals Unit
New Street
Burton -on-trent
United Kingdom
DE14 3QH

Study participating centre
Wrexham Maelor Hospital
Croesnewydd Road
Wrexham Technology Park
Wrexham
United Kingdom
LL13 7TD

Study participating centre
Ysbyty Glan Clwyd
Glan Clwyd Hospital
Rhuddlan Road
Bodelwyddan
Rhyl
United Kingdom
LL18 5UJ

Study participating centre
Ysbyty Gwynedd Hospital (yg NHS Trust)
Ysbyty Gwynedd
Penrhosgarnedd
Bangor
United Kingdom
LL57 2PW

Study participating centre
Pinderfields General Hospital
Aberford Road
Wakefield
United Kingdom
WF1 4DG

Study participating centre
Cumberland Infirmary
Newtown Road
Carlisle
United Kingdom
CA2 7HY

Study participating centre

West Cumberland Hospital
Homewood
Hensingham
Whitehaven
United Kingdom
CA28 8JG

Study participating centre
Warrington Hospital (site)
Warrington Hospital
Lovely Lane
Warrington
United Kingdom
WA5 1QG

Study participating centre
Basildon University Hospital
Nethermayne
Basildon
United Kingdom
SS16 5NL

Study participating centre
Queen Elizabeth Hospital
Sheriff Hill
Gateshead
United Kingdom
NE9 6SX

Study participating centre
Furness General Hospital
Dalton Lane
Barrow-in-furness
United Kingdom
LA14 4LF

Study participating centre
Royal Albert Edward Infirmary
Wigan Lane

Wigan
United Kingdom
WN1 2NN

Study participating centre
University Hospital Crosshouse
Kilmarnock Road
Kilmarnock
United Kingdom
KA2 0BE

Study participating centre
Wishaw General Hospital
50 Netherton Street
Wishaw
United Kingdom
ML2 0DP

Study participating centre
Chesterfield Royal Hospital
Chesterfield Road
Calow
Chesterfield
United Kingdom
S44 5BL

Study participating centre
St Marys Hospital
Parkhurst Road
Newport
United Kingdom
PO30 5TG

Study participating centre
Birmingham Women's Hospital
Mindelsohn Way
Edgbaston
Birmingham
United Kingdom
B15 2TG

Study participating centre
Barnet Hospital
Wellhouse Lane
Barnet
United Kingdom
EN5 3DJ

Study participating centre
The Royal Free Hospital
Pond Street
London
United Kingdom
NW3 2QG

Study participating centre
East Surrey Hospital
Canada Avenue
Redhill
United Kingdom
RH1 5RH

Study participating centre
Yeovil District Hospital
Higher Kingston
Yeovil
United Kingdom
BA21 4AT

Study participating centre
Royal Preston Hospital
Sharoe Green Lane North
Fulwood
Preston
United Kingdom
PR2 4BR

Study participating centre
Birmingham City Hospital
Dudley Road

Birmingham
United Kingdom
B18 7QH

Study participating centre
Arrowe Park Hospital
Arrowe Park Road
Wirral
United Kingdom
CH49 5PE

Study participating centre
Hereford County Hospital
Union Walk
Hereford
United Kingdom
HR1 2ER

Study participating centre
University Hospital of Wales
Heath Park
Cardiff
United Kingdom
CF14 4XW

Study participating centre
James Cook University Hospital
Marton Road
Middlesbrough
United Kingdom
TS4 3BW

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

Study participating centre
Stepping Hill Hospital
Stockport NHS Foundation Trust
Poplar Grove
Hazel Grove
Stockport
United Kingdom
SK2 7JE

Study participating centre
Ipswich Hospital
Heath Road
Ipswich
United Kingdom
IP4 5PD

Study participating centre
Epsom Hospital
Epsom General Hospital
Dorking Road
Epsom
United Kingdom
KT18 7EG

Study participating centre
St Helier Hospital
Wrythe Lane
Carshalton
United Kingdom
SM5 1AA

Study participating centre
Scunthorpe General Hospital
Cliff Gardens
Scunthorpe
United Kingdom
DN15 7BH

Study participating centre
Goole & District Hospital
Woodland Avenue

Goole
United Kingdom
DN14 6RX

Study participating centre
Countess of Chester Hospital
Countess of Chester Health Park
Liverpool Road
Chester
United Kingdom
CH2 1UL

Study participating centre
Milton Keynes General Hospital
Milton Keynes Hospital
Standing Way
Eaglestone
Milton Keynes
United Kingdom
MK6 5LD

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

Study participating centre
Kettering General Hospital
Rothwell Road
Kettering
United Kingdom
NN16 8UZ

Study participating centre
North Tyneside General Hospital
Rake Lane
North Shields
United Kingdom
NE29 8NH

Study participating centre
Northumbria Specialist Emergency Care Hospital
Northumbria Way
Cramlington
United Kingdom
NE23 6NZ

Study participating centre
Wansbeck Hospital
Woodhorn Lane
Ashington
United Kingdom
NE63 9JJ

Study participating centre
James Paget University Hospital
Lowestoft Road
Gorleston
Great Yarmouth
United Kingdom
NR31 6LA

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

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

Study participating centre

Prince Charles Hospital
Merthyr/cynon Unit
Merthyr Tydfil
United Kingdom
CF47 9DT

Study participating centre
Princess of Wales Hospital
Coity Road
Bridgend
Bridgend County Borough
United Kingdom
CF31 1RQ

Study participating centre
Watford General Hospital
60 Vicarage Road
Watford
United Kingdom
WD18 0HB

Study participating centre
West Suffolk Hospital
Hardwick Lane
Bury St. Edmunds
United Kingdom
IP33 2QZ

Study participating centre
Royal Cornwall Hospital (treliske)
Treliske
Truro
United Kingdom
TR1 3LJ

Study participating centre
Whipps Cross University Hospital
Whipps Cross Road
Leytonstone

London
United Kingdom
E11 1NR

Sponsor information

Organisation
University Hospitals Coventry and Warwickshire NHS Trust

Sponsor details
Clifford Bridge Road
Coventry
England
United Kingdom
CV2 2DX
+44 (0)2476 966195
r&dsponsorship@uhcw.nhs.uk

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/025n38288

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care Research

Results and Publications

Publication and dissemination plan
The trialists aim to publish an article in the British Journal of Midwifery. They will also publish the protocol and the final trial results in fully open access high impact peer reviewed journals. They will submit abstracts to major national and international conferences, including RCM, RCPCH annual conferences, RCOG World Congress, and British Maternal and Fetal Medicine conference, for dissemination to service users, researchers, public health and NHS sectors. They will hold three dissemination events in three locations, Manchester, Coventry and London and invite key stakeholders at the end of the study, including participants, representatives from PPI

organisations, clinicians (midwives and doctors) involved in the care of pregnant women, research midwives who worked on the study, managers, policy makers and experts in the field.

Intention to publish date
31/03/2025

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		11/11/2022	14/11/2022	Yes	No
Statistical Analysis Plan	version 4.0	10/02/2023	23/06/2023	No	No
HRA research summary			28/06/2023	No	No
Results article	Cost-effectiveness	01/05/2025	02/05/2025	Yes	No
Results article	Primary results publication	01/05/2025	08/05/2025	Yes	No
Protocol file	version 15.1	05/11/2024	09/05/2025	No	No
Statistical Analysis Plan	Health Economics Analysis Plan version 1.0	05/12/2022	09/05/2025	No	No