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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
05/03/2026

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

Contact information

Type(s)
Public

Contact name
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Coventry
United Kingdom
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Type(s)
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Type(s)
Scientific

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Contact details

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Additional identifiers

Integrated Research Application System (IRAS)
229163

Central Portfolio Management System (CPMS)
36723

National Institute for Health and Care Research (NIHR)
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

Study type(s)
Treatment

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(s)
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

Key secondary outcome(s))
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:
1. Neonatal death
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Infants:
1. Proportion under specialist medical care at 2 months for a problem related to intra-partum experience
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3. In hospital health care costs

Maternal outcomes:
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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
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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

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

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit

100 years

Sex
Female

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
United Kingdom

England

Northern Ireland

Scotland

Wales

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

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

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

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

Study participating centre

Heartland of England NHS Foundation Trust
Bordesley Green East
Birmingham
England
B9 5SS

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

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

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

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

Study participating centre
Huddersfield Royal Infirmary
Woman's Service
Acre Street

Huddersfield
England
HD3 3EA

Study participating centre
Darlington Memorial Hospital
Hollyhurst Road
Darlington
England
DL3 6HX

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

Study participating centre
Burnley General Hospital
Casterton Avenue
Burnley
England
BB10 2PQ

Study participating centre
Royal Blackburn Hospital
Haslingden Road
Blackburn
England
BB2 3HH

Study participating centre
Burnley General Hospital
Woman’s Health - BGH
Casterton Avenue
Burnley
England
BB10 2PQ

Study participating centre
Frimley Park Hospital
Portsmouth Road
Frimley
England
GU16 7UJ

Study participating centre
Wexham Park Hospital
Wexham
Slough
England
SL2 4HL

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

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

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

Study participating centre
St Mary's Hospital
Oxford Road

Manchester
England
M13 9WL

Study participating centre
Leighton Hospital
Leighton
Crewe
England
CW1 4QJ

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

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

Study participating centre
Hinchingbrooke Hospital
Hinchingbrooke Park
Huntingdon
England
PE29 6NT

Study participating centre
Peterborough City Hospital
Edith Cavell Campus
Bretton Gate
Bretton
Peterborough

England
PE3 9GZ

Study participating centre
Salisbury District Hospital
Odstock Road
Salisbury
England
SP2 8BJ

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

Study participating centre
Whiston Hospital
Warrington Road
Prescot
England
L35 5DR

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

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

Study participating centre

The Whittington Hospital
Highgate Hill
London
England
N19 5NF

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

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

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

Study participating centre
The Maidstone Hospital
Hermitage Lane
Maidstone
England
ME16 9QQ

Study participating centre
Tunbridge Wells Hospital
The Tunbridge Wells Hospital
Tonbridge Road
Pembury

Tunbridge Wells
England
TN2 4QJ

Study participating centre
Sunderland Royal Hospital
Kayll Road
Sunderland
England
SR4 7TP

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

Study participating centre
Singleton Hospital
Sketty Lane
Sketty
Swansea
Wales
SA2 8QA

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

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

Study participating centre
Nevill Hall Hospital
Brecon Road
Abergavenny
Wales
NP7 7EG

Study participating centre
York Hospital
Wigginton Road
York
England
YO31 8HE

Study participating centre
Scarborough General Hospital
Woodlands Drive
Scarborough
England
YO12 6QL

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

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

Study participating centre
Victoria Hospital (blackpool)
Whinney Heys Road

Blackpool
England
FY3 8NR

Study participating centre
Hull Royal Infirmary
Anlaby Road
Hull
England
HU3 2JZ

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

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

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

Study participating centre
Worthing Hospital
Lyndhurst Road
Worthing
England
BN11 2DH

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

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

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

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

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

Study participating centre
Cumberland Infirmary
Newtown Road
Carlisle
England
CA2 7HY

Study participating centre
West Cumberland Hospital
Homewood
Hensingham
Whitehaven
England
CA28 8JG

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

Study participating centre
Basildon University Hospital
Nethermayne
Basildon
England
SS16 5NL

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

Study participating centre
Furness General Hospital
Dalton Lane
Barrow-in-furness

England
LA14 4LF

Study participating centre
Royal Albert Edward Infirmary
Wigan Lane
Wigan
England
WN1 2NN

Study participating centre
University Hospital Crosshouse
Kilmarnock Road
Kilmarnock
Scotland
KA2 0BE

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

Study participating centre
Chesterfield Royal Hospital
Chesterfield Road
Calow
Chesterfield
England
S44 5BL

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

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

Study participating centre
Barnet Hospital
Wellhouse Lane
Barnet
England
EN5 3DJ

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

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

Study participating centre
Yeovil District Hospital
Higher Kingston
Yeovil
England
BA21 4AT

Study participating centre
Royal Preston Hospital
Sharoe Green Lane North
Fulwood
Preston

England
PR2 4BR

Study participating centre
Birmingham City Hospital
Dudley Road
Birmingham
England
B18 7QH

Study participating centre
Arrowe Park Hospital
Arrowe Park Road
Wirral
England
CH49 5PE

Study participating centre
Hereford County Hospital
Union Walk
Hereford
England
HR1 2ER

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

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

Study participating centre

Aberdeen Maternity Hospital
Foresterhill
Aberdeen
Scotland
AB25 2ZL

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

Study participating centre
Ipswich Hospital
Heath Road
Ipswich
England
IP4 5PD

Study participating centre
Epsom Hospital
Epsom General Hospital
Dorking Road
Epsom
England
KT18 7EG

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

Study participating centre
Scunthorpe General Hospital
Cliff Gardens
Scunthorpe

England
DN15 7BH

Study participating centre
Goole & District Hospital
Woodland Avenue
Goole
England
DN14 6RX

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

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

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

Study participating centre
Kettering General Hospital
Rothwell Road
Kettering
England
NN16 8UZ

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

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

Study participating centre
Wansbeck Hospital
Woodhorn Lane
Ashington
England
NE63 9JJ

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

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

Study participating centre
Manor Hospital
Moat Road

Walsall
England
WS2 9PS

Study participating centre
Prince Charles Hospital
Merthyr/cynon Unit
Merthyr Tydfil
Wales
CF47 9DT

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

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

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

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

Study participating centre
Whipps Cross University Hospital
Whipps Cross Road
Leytonstone
London
England
E11 1NR

Sponsor information

Organisation
University Hospitals Coventry and Warwickshire NHS Trust

ROR
https://ror.org/025n38288

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from the Warwick Clinical Trials Unit Data Sharing Committee and Chief Investigators.

Requests for data sharing are welcomed from universities, NHS organisations, or companies involved in health and care research, both in the UK and abroad. To ensure the highest standards of data protection and research integrity, the following access criteria apply:
1. Application process: researchers must submit a formal request to the Warwick Clinical Trials Unit (WCTU) Data Sharing Committee via WCTUDataAccess@warwick.ac.uk.
2. Approvals: all requests require approval from the Chief Investigators and the WCTU Data Sharing Committee, as well as evidence of relevant ethical approval for the proposed work.
3. Scope of analysis: data will only be shared for analyses that align with the UK Policy Framework for Health and Social Care Research and serve the public interest.
4. Mechanism: following approval and the execution of a formal Data Sharing Agreement, datasets will be shared via a secure platform implementing appropriate technical and organisational safeguards.

Ethical and legal considerations:
While participants' consent was obtained for the original study, it did not include permission to share confidential patient data. Consequently, all shared data will be fully anonymised. No participant-identifiable information will be released, and the data will not be combined with other sources in a way that could identify individuals. The information is shared solely for health and care research purposes and will have no impact on participants' personal care or future services, such as insurance. Organisations and researchers are strictly prohibited from using this data to contact participants.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
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 article		11/11/2022	14/11/2022	Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file	version 15.1	05/11/2024	09/05/2025	No	No
Statistical Analysis Plan	version 4.0	10/02/2023	23/06/2023	No	No
Statistical Analysis Plan	Health Economics Analysis Plan version 1.0	05/12/2022	09/05/2025	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes