

# Treating people with idiopathic pulmonary fibrosis with the addition of lansoprazole (TIPAL)

<b>Submission date</b> 10/02/2020	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 25/02/2020	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 07/02/2025	<b>Condition category</b> Respiratory	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Idiopathic pulmonary fibrosis (IPF) is a progressive scarring lung condition causing coughing and breathlessness. IPF patients often have reflux disease meaning stomach acid may be breathed into the lungs, potentially damaging them. Medicines that stop stomach acid production, including proton pump inhibitors (PPIs), can be used to reduce reflux symptoms including heartburn. Some researchers suggest PPIs also reduce IPF progression.

This research aims to see if IPF progresses slower if treated with PPIs. Based on the results, the researchers will be able to recommend whether or not IPF patients should take PPIs.

### Who can participate?

Patients aged 40 years or above with a diagnosis of idiopathic pulmonary fibrosis. People taking medicines that interact with PPIs or have other serious medical conditions won't be able to participate. People receiving PPIs will only be able to participate if they can stop taking their medication without their heartburn returning.

### What does the study involve?

At the beginning of the study, the researchers will ask patients to perform breathing tests, and ask those with a cough to use a device to count the number of times they cough in 24 hours. The researchers will ask them to answer two questions rating their coughing and breathlessness, and complete questionnaires on their coughing, IPF, sleep habits and general condition. People will be given a PPI, called lansoprazole, or dummy tablets, twice per day for 12 months. They will be given a leaflet telling them what to do about reflux symptoms. At the end of the study, the researchers will repeat these tests and analyse the results. The researchers will record any side effects people may get. If people suffer side effects, they can reduce the dose.

### What are the possible benefits and risks of participating?

**Benefits:** There is no guarantee that the study will help participants personally, but the information we get from this study will improve our ability to treat patients with pulmonary fibrosis in the future.

**Risks:** Participants may not get the active treatment, lansoprazole, and may receive the dummy

treatment, placebo. However participants will still receive any approved treatment for pulmonary fibrosis from their doctor. Participants will need to attend the hospital for visits in addition to their routine clinic visits. Although participants will receive reimbursement for their travel expenses of up to £100 in total for trial participation. The blood tests may cause discomfort and bruising. Questionnaires will take time to complete. Breathing tests may cause slight breathlessness, difficulty breathing or chest discomfort for a few minutes at the most following the tests. Participants may experience side effects from the active treatment. However, participants are free to reduce their dose of trial treatment under the guidance of their doctor/research team. Participants are also free to withdraw from the study at any time without giving a reason and without any effect on the standard of care participants receive.

Where is the study run from?

Norfolk and Norwich University Hospitals NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?

March 2020 to July 2025

Who is funding the study?

NIHR Evaluation, Trials and Studies Co-ordinating Centre (NETSCC) (UK)

Who is the main contact?

Matthew Hammond, m.hammond@uea.ac.uk, tipal@uea.ac.uk

### **Study website**

<https://www.uea.ac.uk/groups-and-centres/projects/tipal>

## **Contact information**

### **Type(s)**

Public

### **Contact name**

Mr Matthew Hammond

### **Contact details**

NCTU  
Norwich Medical School  
University of East Anglia  
Norwich  
United Kingdom  
NR4 7TJ  
+44 (0)1603591224  
tipal@uea.ac.uk

### **Type(s)**

Scientific

### **Contact name**

Prof Andrew Wilson

### **Contact details**

Norwich Medical School  
University of East Anglia  
Floor 2 Bob Champion Research and Education Building  
Norwich  
United Kingdom  
NR4 7TJ  
+44 (0)1603 591257  
a.m.wilson@uea.ac.uk

## **Additional identifiers**

### **EudraCT/CTIS number**

2020-000041-14

### **IRAS number**

269050

### **ClinicalTrials.gov number**

NCT04965298

### **Secondary identifying numbers**

CPMS 44455, IRAS 269050

## **Study information**

### **Scientific Title**

The effectiveness and risks of Treating people with Idiopathic Pulmonary fibrosis with the Addition of Lansoprazole (TIPAL): a randomised placebo-controlled multi-centre clinical trial

### **Acronym**

TIPAL

### **Study objectives**

Participants treated with lansoprazole will have a smaller absolute decline in percentage predicted (%) FVC at 12 months post-randomisation versus participants treated with placebo.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Approved 29/04/2020, East of England - Cambridgeshire and Hertfordshire Research Ethics Committee (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS, UK; +44 (0)207 104 8106; cambsandherts.rec@hra.nhs.uk), ref: 20/EE/0043

### **Study design**

Interventional randomized controlled trial with a decentralised design

### **Primary study design**

Interventional

## **Secondary study design**

Randomised controlled trial

## **Study setting(s)**

Home, Hospital

## **Study type(s)**

Treatment

## **Participant information sheet**

See study outputs table

## **Health condition(s) or problem(s) studied**

Idiopathic pulmonary fibrosis

## **Interventions**

This project is a clinical trial of an investigational medicinal product (drug). The drug (lansoprazole) is well established and approved for use for another medical condition. The drug will be assessed against placebo (dummy) tablets, with patients allocated to either group by chance. Patients on the drug and dummy tablets will be assessed at the same time. Neither patients nor their doctors or the research team will know which treatment they have been allocated to (although the doctors will be able to find out in an emergency). The researchers will be running the study at approximately 37 hospitals across the UK.

Potentially eligible patients will be approached in clinic or identified from local patient lists /databases. They will be given the relevant study literature to consider participation in the study and will be followed-up by a member of the local research team after they have had at least 24 h to consider participating.

Interested patients will be invited to a screening appointment where they will be counselled on the study and what it entails in order to provide informed consent to participate. The patient will then be asked to complete baseline questionnaires, provide demographic, medical history and concomitant medication, and any other relevant study information, complete a lung function assessment (including spirometry and gas transfer assessments) and provide a blood sample for safety in order for the investigator to confirm their eligibility for the trial. Patients will also provide a blood sample for analysis in future research, a blood sample for genotype analysis and complete a 24-h period of cough frequency monitoring, and activity and sleep monitoring if applicable, if they have consented to do so. Patients in receipt of PPIs without a clear clinical indication for them at consent, will undergo a 2-week wash-out period (following agreement from the patient and their GP) to ascertain whether it is safe to stop this treatment and monitor whether their symptoms subside. Patients who remain asymptomatic at the end of this period will proceed to enter the study. For those whose symptoms return, PPI treatment will recommence and they will not enter the study. Once the results of all baseline assessments are known, patients will be randomised.

Participants will receive an initial 6 month supply of trial medication and be instructed to take 2 tablets twice daily (approximately 12 hours apart), 30 min before meals, for 12 months.

At 3 months post-randomisation, participants will attend the study site again to complete the relevant questionnaires, provide blood samples for safety checks, complete lung function assessments (including spirometry and gas transfer assessments) as before. Participants

involved in the sub-study will again undergo cough frequency monitoring, and activity and sleep monitoring if applicable, for a final 24-h period. Patients will be asked to report any changes in their medical history, medication and any events which they have experienced since their last visit.

Participants will attend the site again at 6 months post-randomisation where they will be required to complete questionnaires, provide a safety blood sample and complete lung function assessments (including spirometry and gas transfer assessments). Participants will again be asked to report any changes in their medical history, medication and any events which they have experienced since their last visit. Participant adherence to the trial medication will be checked via a pill count completed by local site staff. A final supply of trial medication will be dispensed to the patient with the appropriate dosing instructions.

At 9 months post-randomisation, local site staff will contact patients by phone to record any changes in their medical history, medication and any events experienced since their last visit. Patients will be required to complete and return the required questionnaires (electronically or by post) and attend their GP surgery to provide a blood sample for safety checks.

The final study visit occurs 12 months post-randomisation. Patients will be required to complete all necessary questionnaires, provide a blood sample for safety analysis and complete lung function assessments (including spirometry and gas transfer assessments). Participants will also have an additional blood sample taken for analysis in future research studies. Patients will be required to report any changes in their medical history, medication and any events they have experienced since their last report to site staff.

If participants are suspected of or confirmed to have experienced any of the following they may reduce the dose of their trial treatment, at any point during the study, to 1 tablet, twice daily (approximately 12 hours apart), 30 min before meals: respiratory tract infection including pneumonia, Clostridium difficile infection and/or hypomagnesaemia. Participants may also reduce dose if the participant or clinician wishes them to do so.

### **Intervention Type**

Drug

### **Pharmaceutical study type(s)**

Not Applicable

### **Phase**

Phase III

### **Drug/device/biological/vaccine name(s)**

Lansoprazole

### **Primary outcome measure**

Predicted (%) forced vital capacity (FVC) at 12 months post-randomisation

### **Secondary outcome measures**

1. Cough frequency measured using a VitaloJAK cough monitor over a 24-h period at baseline and 3 months post-randomisation
2. Cough score measured using a 100-mm visual analogue scale (VAS) at baseline 3, 6, 9 and 12 months post-randomisation

3. Cough-related quality of life measured by the Leicester Cough Questionnaire at baseline, 3, 6, 9 and 12 months post-randomisation
4. Breathlessness measured by the Medical Research Council (MRC) Dyspnoea Scale at baseline, 3, 6, 9 and 12 months post-randomisation
5. Disease specific quality of life measured using the King's Brief Interstitial Lung Disease (K-BILD) questionnaire at baseline, 3, 6, 9 and 12 months post-randomisation
6. Health related quality of life measured using the EQ-5D-5L questionnaire at baseline, 3, 6, 9 and 12 months post-randomisation (quality-adjusted life-years will be estimated)
7. Adverse events with particular relevance to respiratory tract infection including pneumonia, Clostridium difficile infection and hypomagnesaemia measured at 3, 6, 9 and 12 months post-randomisation
8. Total lung diffusing capacity of carbon monoxide (DLCO) measured at baseline, 3, 6 and 12 months post-randomisation
9. Sleep quality measured by the short Pittsburgh Sleep Quality Index at baseline, 3 and 12 months post-randomisation
10. Reflux characteristics measured by the DeMeester score at baseline, 3 and 12 months post-randomisation
11. Participant acceptability of trial treatment measured by a non-validated study-specific questionnaire at 12 months post-randomisation
12. Risk of sleep apnoea measured by the STOP-bang questionnaire at 12 months post-randomisation
13. Progression free survival (with progression defined as all-cause death, lung transplant, a 10% reduction in FVC % predicted from baseline, or 15% reduction in DLCO % predicted from baseline) at 12 months post-randomisation
14. Hospital-free survival defined as death (all causes) or first non-elective (all-cause) hospital admission at 12 months post-randomisation
15. Respiratory related hospital-free survival at 12 months post-randomisation

**Overall study start date**

01/09/2019

**Completion date**

31/07/2025

## Eligibility

**Key inclusion criteria**

Current inclusion criteria as of 22/08/2023:

1. Male or female, aged greater than or equal to 40 years
2. A diagnosis of Idiopathic Pulmonary Fibrosis (IPF) based on local or regional multi-disciplinary consensus according to the latest international guidelines
3. Patients may be receiving licensed anti-fibrotic medication (for at least 4 weeks prior to randomisation with no planned amendments for at least 4 weeks post-randomisation)
4. Able to provide informed consent

Additional inclusion criteria for cough count sub-study:

1. Pre-existing diagnosis of persistent cough (defined as troublesome for more than 8 weeks prior to study enrolment)

Previous inclusion criteria:

1. Male or female, aged greater than or equal to 40 years

2. A diagnosis of Idiopathic Pulmonary Fibrosis (IPF) based on local or regional multi-disciplinary consensus according to the latest international guidelines (Am J Respir Crit Care Med. 2018;198: e44-e68)
3. Patients may be receiving licensed anti-fibrotic medication (for at least 4 weeks prior to randomisation with no planned amendments for at least 4 weeks post-randomisation)
4. Able to provide informed consent

Additional inclusion criteria for cough count sub-study:

1. Pre-existing diagnosis of persistent cough (defined as troublesome for more than 8 weeks prior to study enrolment)

### **Participant type(s)**

Patient

### **Age group**

Adult

### **Lower age limit**

40 Years

### **Sex**

Both

### **Target number of participants**

Planned Sample Size: 298; UK Sample Size: 298

### **Key exclusion criteria**

Current exclusion criteria as of 22/08/2023:

1. Patients unable to complete reliable FVC measurements (i.e. the difference between the two largest values is NOT  $\leq 0.150$  L)
2. Concomitant use of a proton pump inhibitor (PPI) or prokinetic drugs (cisapride, domperidone, metoclopramide, erythromycin, pruclopride etc) within 2 weeks prior to randomisation
3. Patients with a self-reported significant respiratory tract infection, including COVID-19, within 4 weeks of screening.
4. Significant co-existing respiratory disease (defined as a respiratory condition that exhibits a clinically relevant effect on respiratory symptoms and disease progression as determined by the PI). The presence of bronchiectasis is permitted
5. Patients with  $FEV_1/FVC < 0.7$
6. Significant medical, surgical or psychiatric disease that in the opinion of the patient's attending physician would affect subject safety or influence the study outcomes including liver failure (e.g. serum transaminase  $> 2x$  upper limit of normal (ULN), bilirubin  $> 1.5x$  ULN (unless the patient has Gilbert's syndrome) and chronic kidney disease (CKD) no greater than stage 3 (stable for at least 3 months prior to enrolment), erosive oesophagitis, Barrett's oesophagus or any other condition requiring lifelong proton pump inhibitor use.
7. Known allergy to proton pump inhibitors or the contents of placebo
8. Concomitant use of atazanavir, ketoconazole, itraconazole, tacrolimus, methotrexate, fluvoxamine (see section 6.4.5 of protocol)
9. Females who are of childbearing potential or lactating. Non-childbearing potential is defined as follows: postmenopausal females who have had at least 12 months of spontaneous amenorrhoea or 6 months of spontaneous amenorrhoea with serum FSH  $> 40$  mIU/ml or females who have had a hysterectomy, bilateral salpingectomy or bilateral oophorectomy at least 6

weeks prior to enrolment

10. Receipt of another investigational drug or biological agent associated with another clinical trial within the 4 weeks prior to TIPAL study enrolment or 5 times the drug half-life, whichever is the longer

11. Receiving long-term oxygen therapy

12. Patients with hypomagnesaemia (defined as magnesium  $< = 0.6\text{mmol/L}$ )

Previous exclusion criteria:

1. Patients unable to complete reliable FVC measurements (i.e. the difference between the two largest values is NOT  $< = 0.150\text{ L}$ )

2. Concomitant use of a proton pump inhibitor (PPI) or prokinetic drugs (cisapride, domperidone, metoclopramide, erythromycin, pruclopride etc) within 2 weeks prior to randomisation

3. Patients with a self-reported respiratory tract infection within 4 weeks of screening (defined as two or more of: increased cough, sputum or breathlessness and requiring antimicrobial therapy)

4. Significant co-existing respiratory disease (defined as a respiratory condition that exhibits a clinically relevant effect on respiratory symptoms and disease progression as determined by the PI). The presence of bronchiectasis is permitted

5. Patients with  $\text{FEV1/FVC} < 0.7$

6. Significant medical, surgical or psychiatric disease that in the opinion of the patient's attending physician would affect subject safety or influence the study outcomes including liver failure (e.g. serum transaminase  $> 2\times$  upper limit of normal (ULN), bilirubin  $> 1.5\times$  ULN (unless the patient has Gilbert's syndrome) and chronic kidney disease (CKD) no greater than stage 3 (stable for at least 3 months prior to enrolment), erosive oesophagitis, Barrett's oesophagus or any other condition requiring lifelong proton pump inhibitor use.

7. Known allergy to proton pump inhibitors or the contents of placebo

8. Concomitant use of atazanavir, ketoconazole, itraconazole, tacrolimus, methotrexate, fluvoxamine (see section 6.4.5 of protocol)

9. Females who are of childbearing potential or lactating. Non-childbearing potential is defined as follows: postmenopausal females who have had at least 12 months of spontaneous amenorrhoea or 6 months of spontaneous amenorrhoea with serum FSH  $> 40\text{mIU/ml}$  or females who have had a hysterectomy, bilateral salpingectomy or bilateral oophorectomy at least 6 weeks prior to enrolment

10. Receipt of another investigational drug or biological agent associated with another clinical trial within the 4 weeks prior to TIPAL study enrolment or 5 times the drug half-life, whichever is the longer

11. Receiving long-term oxygen therapy

12. Patients with hypomagnesaemia (defined as magnesium  $< = 0.6\text{mmol/L}$ )

**Date of first enrolment**

16/06/2021

**Date of final enrolment**

31/08/2024

## Locations

**Countries of recruitment**

England

Northern Ireland



Scotland

United Kingdom

Wales

**Study participating centre**

**Norfolk and Norwich University Hospital**

Colney Lane

Norwich

United Kingdom

NR4 7UY

**Study participating centre**

**Queen Elizabeth Hospital Birmingham**

University Hospitals Birmingham NHS Foundation Trust

Mindelsohn Way

Birmingham

United Kingdom

B15 2TH

**Study participating centre**

**Central Manchester University Hospitals NHS Foundation Trust**

Cobbett House

Oxford Road

Manchester

United Kingdom

M13 9WL

**Study participating centre**

**University Hospital Aintree**

Aintree University Hospital Nhs Foundation Trust

Fazakerley Hospital

Lower Lane Liverpool

Merseyside

Liverpool

United Kingdom

L9 7AL

**Study participating centre**

**Royal Papworth Hospital Nhs Foundation Trust**

Papworth Everard  
Cambridge  
United Kingdom  
CB23 3RE

**Study participating centre**

**Royal Brompton Hospital**

Royal Brompton and Harefield NHS Foundation Trust  
Sydney Street  
London  
United Kingdom  
SW3 6NP

**Study participating centre**

**Freeman Hospital**

Freeman Road  
High Heaton  
Newcastle upon Tyne  
United Kingdom  
NE7 7DN

**Study participating centre**

**Western Health & Social Care Trust**

MDEC Building  
Glenshane Road  
Derry  
United Kingdom  
BT47 6SB

**Study participating centre**

**Leicester Royal Infirmary**

Infirmary Square  
Leicester  
United Kingdom  
LE1 5WW

**Study participating centre**

**Westmorland General Hospital**

University Hospitals of Morecambe Bay NHS Foundation Trust  
Burton Road

Kendal  
United Kingdom  
LA9 7RG

**Study participating centre**

**Southmead Hospital**  
North Bristol NHS Trust  
Southmead Road  
Westbury-on-trym  
Bristol  
United Kingdom  
BS10 5NB

**Study participating centre**

**New Cross Hospital**  
The Royal Wolverhampton Nhs Trust  
Wolverhampton Road  
Heath Town  
Wolverhampton  
United Kingdom  
WV10 0QP

**Study participating centre**

**Northern General Hospital**  
Sheffield Teaching Hospitals Nhs Foundation Trust  
Herries Road  
Sheffield  
United Kingdom  
S5 7AU

**Study participating centre**

**South Tyneside District Hospital**  
South Tyneside Nhs Foundation Trust  
Harton Lane  
South Shields  
United Kingdom  
NE34 0PL

**Study participating centre**

**Worcestershire Royal Hospital**  
Worcestershire Acute Hospitals Nhs Trust

Charles Hastings Way  
Worcester  
United Kingdom  
WR5 1DD

**Study participating centre**  
**Sherwood Forest Hospitals Nhs Foundation Trust**  
Mansfield Road  
Sutton-in-Ashfield  
United Kingdom  
NG17 4JL

**Study participating centre**  
**Victoria Hospital**  
Blackpool Teaching Hospitals Nhs Foundation Trust  
Whinney Heys Road  
Blackpool  
United Kingdom  
FY3 8NR

**Study participating centre**  
**St. Marys Hospital**  
Imperial College Healthcare Nhs Trust  
Praed Street  
London  
United Kingdom  
W2 1NY

**Study participating centre**  
**Nhs Grampian**  
Summerfield House  
2 Eday Road  
Aberdeen  
United Kingdom  
AB15 6RE

**Study participating centre**  
**Southampton General Hospital**  
University Hospital Southampton Nhs Foundation Trust  
Tremona Road  
Southampton

United Kingdom  
SO16 6YD

**Study participating centre**

**Leighton Hospital**

Mid Cheshire Hospitals Nhs Foundation Trust  
Leighton  
Crewe  
United Kingdom  
CW1 4QJ

**Study participating centre**

**Royal Preston Hospital**

Lancashire Teaching Hospitals Nhs Foundation Trust  
Sharoe Green Lane  
Fulwood  
Preston  
United Kingdom  
PR2 9HT

**Study participating centre**

**Hull Royal Infirmary**

Hull and East Yorkshire Hospitals Nhs Trust  
Anlaby Road  
Hull  
United Kingdom  
HU3 2JZ

**Study participating centre**

**Shrewsbury And Telford Hospital Nhs Trust**

Mytton Oak Road  
Shrewsbury  
United Kingdom  
SY3 8XQ

**Study participating centre**

**Cardiff & Vale University LHB**

Heath Park  
Cardiff  
United Kingdom  
CF14 4XW

**Study participating centre**

**John Radcliffe Hospital**

Oxford University Hospitals Nhs Foundation Trust  
Headley Way  
Headington  
Oxford  
United Kingdom  
OX3 9DU

**Study participating centre**

**Royal Infirmary**

Calderdale and Huddersfield Nhs Foundation Trust  
Acre Street  
Huddersfield  
United Kingdom  
HD3 3EA

**Study participating centre**

**University College London Hospitals Nhs Foundation Trust**

250 Euston Road  
London  
United Kingdom  
NW1 2PG

**Study participating centre**

**Queens Medical Centre**

Nottingham University Hospitals Nhs Trust  
Derby Road  
Nottingham  
United Kingdom  
NG7 2UH

**Study participating centre**

**University Hospitals of North Midlands Nhs Trust**

Newcastle Road  
Stoke-on-Trent  
United Kingdom  
ST4 6QG

**Study participating centre**  
**The Royal London Hospital**  
Barts Health Nhs Trust  
Whitechapel  
London  
United Kingdom  
E1 1BB

**Study participating centre**  
**Heartlands Hospital**  
Bordesley Green East  
Bordesley Green  
Birmingham  
United Kingdom  
B9 5SS

**Study participating centre**  
**Royal Albert Edward Infirmary**  
Wigan Lane  
Wigan  
United Kingdom  
WN1 2NN

**Study participating centre**  
**Northumbria Healthcare NHS Foundation Trust**  
North Tyneside General Hospital  
Rake Lane  
North Shields  
United Kingdom  
NE29 8NH

**Study participating centre**  
**Craigavon Area Hospital**  
Lurgan Rd  
Craigavon  
United Kingdom  
BT63 5QQ

**Study participating centre**

**Antrim Area Hospital**

45 Bush Rd

Antrim

United Kingdom

BT41 2RL

**Study participating centre****Perth Royal Infirmary**

Taymount Terrace

Perth

United Kingdom

PH1 1NX

**Study participating centre****Ninewells Hospital**

Ninewells Avenue

Dundee

United Kingdom

DD1 9SY

**Study participating centre****Musgrove Park Hospital (taunton)**

Musgrove Park Hospital

Taunton

United Kingdom

TA1 5DA

**Study participating centre****St James's University Hospital NHS Trust**

St James's University Hospital

Gledow Wing

Beckett Street

Leeds

United Kingdom

LS9 7TF

**Study participating centre****Macclesfield District General Hospital**

Macclesfield District Hospital

Victoria Road

Macclesfield



United Kingdom  
SK10 3BL

**Study participating centre**  
**North Tees Health NHS Trust**  
North Tees General Hospital  
Hardwick  
Stockton-on-tees  
United Kingdom  
TS19 8PE

**Study participating centre**  
**Lewisham and Greenwich NHS Trust**  
University Hospital Lewisham  
Lewisham High Street  
London  
United Kingdom  
SE13 6LH

**Study participating centre**  
**Luton and Dunstable University Hospital**  
Lewsey Road  
Luton  
United Kingdom  
LU4 0DZ

**Study participating centre**  
**Hywel Dda Health Board**  
Hafan Derwen  
St Davids Parc  
Job's Well Road  
Carmarthen  
United Kingdom  
SA31 3BB

**Study participating centre**  
**Basingstoke and North Hampshire Hospital**  
Aldermaston Road  
Basingstoke  
United Kingdom  
RG24 9NA

**Study participating centre**  
**Royal Hampshire County Hospital (rhch)**  
Romsey Road  
Winchester  
United Kingdom  
SO22 5DG

**Study participating centre**  
**Torbay and South Devon NHS Foundation Trust**  
Torbay Hospital  
Newton Road  
Torquay  
United Kingdom  
TQ2 7AA

**Study participating centre**  
**The Guys and Lewisham NHS Trust**  
Guys Hospital  
St Thomas Street  
London  
United Kingdom  
SE1 9RT

**Study participating centre**  
**Royal United Hospital**  
Combe Park  
Bath  
United Kingdom  
BA1 3NG

**Study participating centre**  
**Maidstone and Tunbridge Wells NHS Trust**  
The Maidstone Hospital  
Hermitage Lane  
Maidstone  
United Kingdom  
ME16 9QQ

**Study participating centre**

**Portsmouth Hospitals University National Health Service Trust**

Queen Alexandra Hospital  
Southwick Hill Road  
Cosham  
Portsmouth  
United Kingdom  
PO6 3LY

**Study participating centre**

**East and North Hertfordshire NHS Trust**

Lister Hospital  
Coreys Mill Lane  
Stevenage  
United Kingdom  
SG1 4AB

**Study participating centre**

**Royal Blackburn Hospital**

Haslingden Road  
Blackburn  
United Kingdom  
BB2 3HH

**Study participating centre**

**Burnley General Hospital**

Casterton Avenue  
Burnley  
United Kingdom  
BB10 2PQ

**Study participating centre**

**Frimley Park Hospital**

Frimley Park Scanning Centre  
Portsmouth Road  
Frimley  
Camberley  
United Kingdom  
GU16 7UJ

**Study participating centre**

**Kingston Hospital**  
Galsworthy Road  
Kingston upon Thames  
United Kingdom  
KT2 7QB

**Study participating centre**  
**Doncaster and Bassetlaw Teaching Hospitals NHS Foundation Trust**  
Doncaster Royal Infirmary  
Armthorpe Road  
Doncaster  
United Kingdom  
DN2 5LT

**Study participating centre**  
**North Middlesex University Hospital Trust**  
North Middlesex Hospital  
Sterling Way  
London  
United Kingdom  
N18 1QX

**Study participating centre**  
**The Princess Alexandra Hospital**  
Hamstel Road  
Harlow  
United Kingdom  
CM20 1QX

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

## **Sponsor information**

**Organisation**

Norfolk and Norwich University Hospitals NHS Foundation Trust

**Sponsor details**

Colney Lane  
Colney  
Norwich  
England  
United Kingdom  
NR4 7UY  
+44 (0)1603 647882  
julie.dawson@nnuh.nhs.uk

**Sponsor type**

Hospital/treatment centre

**Website**

<http://www.nnuh.nhs.uk/>

**ROR**

<https://ror.org/01wspv808>

**Funder(s)**

**Funder type**

Government

**Funder Name**

NIHR Evaluation, Trials and Studies Co-ordinating Centre (NETSCC); Grant Codes: NIHR127479

**Funder Name**

National Institute for Health Research (NIHR) (UK)

**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

## Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal.

## Intention to publish date

31/08/2025

## Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request.

## IPD sharing plan summary

Available on request

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Protocol file</a>	version v2.1	23/03/2021	12/04/2021	No	No
<a href="#">HRA research summary</a>			28/06/2023	No	No
<a href="#">Participant information sheet</a>	version 2.6	11/08/2022	22/08/2023	No	Yes
<a href="#">Protocol article</a>		05/02/2025	07/02/2025	Yes	No