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

Submission date	**Recruitment status**	[X] Prospectively registered
10/02/2020	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
25/02/2020	Ongoing	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
09/07/2026	Respiratory	[X] 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 24hours. 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 May 2027

Who is funding the study?
NIHR Evaluation, Trials and Studies Co-ordinating Centre (NETSCC) (UK)

Who is the main contact?
tipal@uea.ac.uk

Contact information

Type(s)
Public

Contact name
Miss Izobel Clegg

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

ClinicalTrials.gov (NCT)
NCT04965298

Clinical Trials Information System (CTIS)
2020-000041-14

Integrated Research Application System (IRAS)
269050

Central Portfolio Management System (CPMS)
44455

National Institute for Health and Care Research (NIHR)
127479

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

Primary study design
Interventional

Study design
Interventional randomized controlled trial with a decentralised design

Study type(s)
Treatment

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

Phase
Phase III

Drug/device/biological/vaccine name(s)
Lansoprazole

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

Key secondary outcome(s)
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

Completion date
31/05/2027

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

Healthy volunteers allowed

No

Age group
Mixed

Lower age limit
40 Years

Upper age limit
100 Years

Sex
All

Total final enrolment
299

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 < = 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 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 > 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> 40mlU/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 hypomagesmesmia (defined as magnesium < = 0.6mmol/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 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 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 > 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.
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11. Receiving long-term oxygen therapy
12. Patients with hypomagesmesmia (defined as magnesium < = 0.6mmol/L)

Date of first enrolment
16/06/2021

Date of final enrolment
23/06/2026

Locations

Countries of recruitment
United Kingdom

England

Northern Ireland

Scotland

Wales

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

Study participating centre
Queen Elizabeth Hospital Birmingham
University Hospitals Birmingham NHS Foundation Trust
Mindelsohn Way
Birmingham
England
B15 2TH

Study participating centre
Central Manchester University Hospitals NHS Foundation Trust
Cobbett House
Oxford Road
Manchester
England
M13 9WL

Study participating centre
University Hospital Aintree
Aintree University Hospital Nhs Foundation Trust
Fazakerley Hospital
Lower Lane Liverpool
Merseyside
Liverpool
England
L9 7AL

Study participating centre
Royal Papworth Hospital Nhs Foundation Trust
Papworth Everard
Cambridge
England
CB23 3RE

Study participating centre

Royal Brompton Hospital
Royal Brompton and Harefield NHS Foundation Trust
Sydney Street
London
England
SW3 6NP

Study participating centre
Freeman Hospital
Freeman Road
High Heaton
Newcastle upon Tyne
England
NE7 7DN

Study participating centre
Western Health & Social Care Trust
MDEC Building
Glenshane Road
Derry
Northern Ireland
BT47 6SB

Study participating centre
Leicester Royal Infirmary
Infirmary Square
Leicester
England
LE1 5WW

Study participating centre
Westmorland General Hospital
University Hospitals of Morecambe Bay NHS Foundation Trust
Burton Road
Kendal
England
LA9 7RG

Study participating centre
Southmead Hospital
North Bristol NHS Trust

Southmead Road
Westbury-on-trym
Bristol
England
BS10 5NB

Study participating centre
New Cross Hospital
The Royal Wolverhampton Nhs Trust
Wolverhampton Road
Heath Town
Wolverhampton
England
WV10 0QP

Study participating centre
Northern General Hospital
Sheffield Teaching Hospitals Nhs Foundation Trust
Herries Road
Sheffield
England
S5 7AU

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

Study participating centre
Worcestershire Royal Hospital
Worcestershire Acute Hospitals Nhs Trust
Charles Hastings Way
Worcester
England
WR5 1DD

Study participating centre

Sherwood Forest Hospitals Nhs Foundation Trust
Mansfield Road
Sutton-in-Ashfield
England
NG17 4JL

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

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

Study participating centre
Nhs Grampian
Summerfield House
2 Eday Road
Aberdeen
Scotland
AB15 6RE

Study participating centre
Southampton General Hospital
University Hospital Southampton Nhs Foundation Trust
Tremona Road
Southampton
England
SO16 6YD

Study participating centre
Leighton Hospital
Mid Cheshire Hospitals Nhs Foundation Trust

Leighton
Crewe
England
CW1 4QJ

Study participating centre
Royal Preston Hospital
Lancashire Teaching Hospitals Nhs Foundation Trust
Sharoe Green Lane
Fulwood
Preston
England
PR2 9HT

Study participating centre
Hull Royal Infirmary
Hull and East Yorkshire Hospitals Nhs Trust
Anlaby Road
Hull
England
HU3 2JZ

Study participating centre
Shrewsbury And Telford Hospital Nhs Trust
Mytton Oak Road
Shrewsbury
England
SY3 8XQ

Study participating centre
Cardiff & Vale University LHB
Heath Park
Cardiff
Wales
CF14 4XW

Study participating centre
John Radcliffe Hospital
Oxford University Hospitals Nhs Foundation Trust
Headley Way
Headington

Oxford
England
OX3 9DU

Study participating centre
Royal Infirmary
Calderdale and Huddersfield Nhs Foundation Trust
Acre Street
Huddersfield
England
HD3 3EA

Study participating centre
University College London Hospitals Nhs Foundation Trust
250 Euston Road
London
England
NW1 2PG

Study participating centre
Queens Medical Centre
Nottingham University Hospitals Nhs Trust
Derby Road
Nottingham
England
NG7 2UH

Study participating centre
University Hospitals of North Midlands Nhs Trust
Newcastle Road
Stoke-on-Trent
England
ST4 6QG

Study participating centre
The Royal London Hospital
Barts Health Nhs Trust
Whitechapel
London
England
E1 1BB

Study participating centre
Heartlands Hospital
Bordesley Green East
Bordesley Green
Birmingham
England
B9 5SS

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

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

Study participating centre
Craigavon Area Hospital
Lurgan Rd
Craigavon
Northern Ireland
BT63 5QQ

Study participating centre
Antrim Area Hospital
45 Bush Rd
Antrim
Northern Ireland
BT41 2RL

Study participating centre

Perth Royal Infirmary
Taymount Terrace
Perth
Scotland
PH1 1NX

Study participating centre
Ninewells Hospital
Ninewells Avenue
Dundee
Scotland
DD1 9SY

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

Study participating centre
St James's University Hospital NHS Trust
St James's University Hospital
Gledow Wing
Beckett Street
Leeds
England
LS9 7TF

Study participating centre
Macclesfield District General Hospital
Macclesfield District Hospital
Victoria Road
Macclesfield
England
SK10 3BL

Study participating centre
North Tees Health NHS Trust
North Tees General Hospital
Hardwick

Stockton-on-tees
England
TS19 8PE

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

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

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

Study participating centre
Basingstoke and North Hampshire Hospital
Aldermaston Road
Basingstoke
England
RG24 9NA

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

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

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

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

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

Study participating centre
Portsmouth Hospitals University National Health Service Trust
Queen Alexandra Hospital
Southwick Hill Road
Cosham
Portsmouth
England
PO6 3LY

Study participating centre
East and North Hertfordshire NHS Trust
Lister Hospital
Coreys Mill Lane
Stevenage
England
SG1 4AB

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

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

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

Study participating centre
Kingston Hospital
Galsworthy Road
Kingston upon Thames
England
KT2 7QB

Study participating centre

Doncaster and Bassetlaw Teaching Hospitals NHS Foundation Trust
Doncaster Royal Infirmary
Armthorpe Road
Doncaster
England
DN2 5LT

Study participating centre
North Middlesex University Hospital Trust
North Middlesex Hospital
Sterling Way
London
England
N18 1QX

Study participating centre
The Princess Alexandra Hospital
Hamstel Road
Harlow
England
CM20 1QX

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

Sponsor information

Organisation
Norfolk and Norwich University Hospitals NHS Foundation Trust

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

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?
Protocol article		05/02/2025	07/02/2025	Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	version 2.6	11/08/2022	22/08/2023	No	Yes
Participant information sheet	version 2.8	14/10/2024	09/07/2026	No	Yes
Protocol file	version v2.1	23/03/2021	12/04/2021	No	No
Protocol file	version 2.4	23/03/2023	09/07/2026	No	No
Study website		11/11/2025	11/11/2025	No	Yes