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

Submission date 10/02/2020	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 25/02/2020	**Overall study status** Completed	
Last Edited 07/02/2025	**Condition category** Respiratory	

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 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

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Additional identifiers

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

Integrated Research Application System (IRAS)
269050

ClinicalTrials.gov (NCT)
NCT04965298

Protocol serial number
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

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
31/07/2025

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
40 years

Sex
All

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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Date of first enrolment
16/06/2021

Date of final enrolment
31/08/2024

Locations

Countries of recruitment
United Kingdom

England

Northern Ireland

Scotland

Wales

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Norfolk and Norwich University Hospital
Colney Lane
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Study participating centre

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SW3 6NP

Study participating centre

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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
Protocol file	version v2.1	23/03/2021	12/04/2021	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes