TRIAL SUMMARY

Title:

Ambulatory Oxgyen Therapy for Pulmonary Fibrosis (OXYPuF)

Primary Objective:

To determine what is the clinical and cost effectiveness of ambulatory oxygen therapy (AOT) in patients with idiopathic pulmonary fibrosis (IPF).

Secondary Objectives:

- Determine whether breathlessness, determined by the King's Brief Interstitial Lung Disease (K-BILD), and MRC score, is superior after AOT compared to best supportive care at 6 months
- Determine whether exercise capacity and physical activity, as described by the six minute walk test (6MWT) or a sit to stand test (depending on local policy), and a self reported activity questionnaire (IPAQ) respectively, is superior after AOT compared to best supportive care at 6 months
- Assess the acceptability of AOT

Trial Design

A multicentre randomised controlled, open-label, pragmatic clinical trial designed to test both the clinical and cost effectiveness of AOT in patients with IPF.

Participant Population and Sample Size

260 consenting adults diagnosed with IPF confirmed via a multidisciplinary team meeting or an IPF specialist.

Eligibility Criteria:

Inclusion

- Clinically diagnosed IPF, confirmed by an ILD MDT linked to an NHS specialist commissioned IPF service
- Breathlessness with MRC dyspnoea score ≥2

Exclusion Criteria

- Unable to adequately consent
- Requiring LTOT, defined by need for resting oxygen in opinion of local investigator. Blood gases will only be required by the protocol at screening if saturations are <90% on air, as per usual care
- Unable to complete a 6MWT OR sit to stand test
- Unsafe to use oxygen for any reason in the opinion of the local investigator(eg current smokers)
- Life expectancy < 6 months
- On active transplant list
- Previous acidotic hypercapnic respiratory failure requiring NIV (AHRF)

Interventions Arm

Ambulatory Oxygen Therapy and standardised breathlessness Advice.

Control Arm

Standardised breathlessness advice.

Outcome Measures:

Primary Outcome

K-BILD score after 6 months.

Secondary Outcomes

- Subscales within K-BILD (breathlessness, activity, chest symptoms);
- EQ5D-5L;
- Exercise capacity (6MWT or 1 minute sit to stand)
- Physical activity (international physical activity questionnaire (IPAQ (43),
- Epworth score

- Accelerometry in a subset of 20% of patients);
- Hospitalisations (all cause and IPF specific);
- Targeted adverse events
- Mortality (6 months, and from medical record only at 12 months);
- Medication use, (in particular benzodiazepines and opiates for breathlessness);
- Scheduled and unscheduled health service use;
- Completion of pulmonary rehabilitation;

Trial Schema