e-Lung

Differences in e-Lung biomarker scores between treatment groups in post-hoc analysis of the ATLAS inhaled pirfenidone solution (AP01) for IPF clinical trial

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Rationale & Methods

- The weighted reticulovascular score (WRVS) is an automated CT biomarker of lung fibrosis
- WRVS quantifies a combination of reticulation and vascular structures (Figure 1)
- e-Lung imaging biomarkers were studied in a post-hoc analysis of a phase 1b clinical trial of inhaled pirfenidone (ATLAS study) in patients with idiopathic pulmonary fibrosis (IPF)

Patient Demographics

- 63 patients
- 100mg BD, n=28
- 50mg OD, n=35

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Results

- e-Lung volume correlated strongly with FVC (r=0.85, p<0.001)
- In patients who received 50mg OD, baseline WRVS was associated with 5% FVC decline (OR 4.89 (1.14 to 26.7), p=0.044)
- Adjusting for baseline WRVS, 100mg BD dose associated with mean relative decrease in WRVS of -0.8% (-5.5% to +3.9%) vs. mean relative increase in WRVS of +5.3% (+1.2% to +9.5%) in the 50mg OD group (p=0.06) (Figure 2)
- This mirrored trends in mean relative FVC change of +0.6% (-2.7% to +3.9%) in the 100mg BD group vs –2.6% (-5.6% to +0.4%) in the 50mg OD group (p=0.07) (Figure 2)

Figure 1

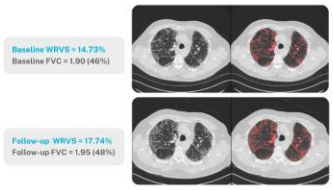

Figure 1 Legend: Patient on 50mg once daily of nebulised pirfenidone. Stable FVC comparing baseline and 36 weeks. Rise in WRVS between baseline and follow-up CT and evidence of increased fibrosis on visual evaluation in line with progression of IPF

Figure 2

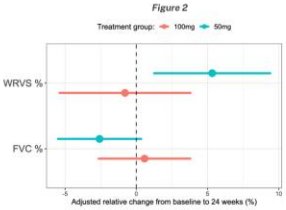

Figure 2 Legend: Relative change in WRVS and FVC between Baseline and 24-week timepoint

Conclusions

- e-Lung WRVS was associated with risk of future IPF progression in the low-dose pirfenidone group
- WRVS can identify treatment effects on CT, potentially even when the FVC is stable
- This research can assist in the optimisation of AI imaging tools to enrich clinical trials for progressive patients, to facilitate matching treatment arms and further explore novel trial end points

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