



Impact of one year of treatment with Elexacaftor-Tezacaftor-Ivacaftor on clinical outcomes in people with CF in a real world setting – The RECOVER study

McNally, P. ^{1,2}, Fleming, A.^{1,2}, Elnazir, B.², Williamson, M.², Cox, D.², Linnane, B.³, Kirwan, L.⁴, Saunders, C.⁵, Tiddens, HAWM.⁶, Grasemann, H.⁷, McKone, E. F.⁸, Davies, J. C.^{5,9}On behalf of the RECOVER study Group

¹RCSI University, Dublin, Ireland. ²Children's Health Ireland, Dublin, Ireland. ³University of Limerick School of Medicine, Limerick, Ireland. ⁴Cystic Fibrosis Registry of Ireland. ⁵Royal Brompton & Harefield hospitals, part of Guys and St Thomas' Trust, London, UK. ⁶Erasmus Medical Centre, Rotterdam, Netherlands. ⁷Hospital for Sick Children, Toronto, Canada. ⁸St Vincent's University Hospital, Dublin, Ireland. ⁹NHLI Imperial College London, UK.







Children's Health Ireland

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Conclusion:

ELX/TEZ/IVA is associated with significant and sustained improvements in an array of outcome measures over 1 year in people with CF. A significant proportion (40%) of people in the FF group had a sweat chloride in the normal range on treatment. Data collection is continuing for RECOVER.

Hear the full presentation at Workshop 6 Thursday 9th June



N=32







Sharon Sutton^{1,2}, John Hayden², Moninne Howlett^{1,2}, Jane Davies⁵, Aine Fleming², Basil Elnazir^{1,8}, Michael Williamson¹, Edward McKone⁶, Des Cox¹, Barry Linnane⁷, Alexandra Quittner^{3,4} and Paul McNally^{1,2}

A Real-world Study Evaluating the Impact of Elexacaftor-Tezacaftor-Ivacaftor Treatment on Medication Adherence in Cystic Fibrosis

RESULTS

Recruitment commenced in September 2020. To date, 116 participants have been recruited to the 12+ cohort. Available baseline and 6 month data are presented below.

Self Report Questionnaires

Adherence to modulators was high from self-reported questionnaires (TAQ and PTP) (see figure 1). Early baseline and 6-month suggest reductions in adherence to dornase alpha (85% to 81%, p=0.08), Hypertonic saline (90% to 79%, p=0.08) and airway clearance (80% to 66%,p=0.03) on introduction of ETI.

1 Children's Health Ireland, Dublin, Ireland. 2 RCSI University, Dublin, Ireland. 3 Nicklaus Children's Hospital, Florida, USA. 4 University of Miami, Florida, USA. 5 Imperial College London, UK. 6 St Vincent's University Hospital, Dublin, Ireland. 7 University of Limerick School of Medicine, Limerick, Ireland. 8 Trinity College Dublin, Ireland.

BACKGROUND

RECOVER The study IS nona interventional world real study examining the impact of Elexacaftor-Tezacaftor-lvacaftor (ETI) therapy on disease outcomes medication and adherence.

AIM

To measure the impact of ETI initiation on Cystic Fibrosis (CF) therapy



Figure 1. Overall adherence at 6 months as per TAQ data pre and post introduction of Elexacaftor/Tezacaftor/Ivacaftor and overall average adherence using MEMS[®]

adherence.

METHODS

Two phase multi-site (n=8) noninterventional study of CF clinical outcomes in patients prescribed ETI across Ireland and the UK. Adherence in two cohorts based on ETI licensing $(12+: patients \geq 12 years; 6+: \geq 6-<12$ years) will be measured over 2 years using 3 methods: 1. Treatment Adherence Questionnaire (TAQ) and Adherence Barrier Questionnaires (ABQ) – both self-reported; 2. Medication Possession Ratio (MPR) calculated from pharmacy refill data; 3. Medication Electronic and Monitoring System (MEMS[®]) - subset of participants in both cohorts only.

Medication Electronic Monitoring Systems®

Initial recruitment for MEMS[®] was high with 60% (n=23) remaining. The preliminary results from a subset of participants (n=18) indicate that adherence is suboptimal; overall average adherence is 69.8% and adherence to 73.2% for ETI (n=18) and 66.3% for Ivacaftor (n=18), respectively.

Medication Possession Ratio (MPR)

Medications	Medication Possession Ratio		P-value
	Baseline	6 Months	
CFTR Modulators	94.53%	86.09%	0.05
Azithromycin	68.90%	45.82%	0.09
Hypertonic Saline	55.25%	41.56%	0.20
Dornase Alpha	72.03%	67.12%	0.37
Creon 10,000	65.82%	60.9%	0.42

Table 1. MPR data at Baseline and 6 months. Baseline MPR of hypertonic saline, azithromycin, enzymes (Creon[®] 10000) and dornase alpha was low to moderate. 6 month data suggest MPRs further reduce.

CONCLUSION

Early preliminary results suggest ETI adherence is overestimated in SRQs and MPR data compared to MEMS[®]. These trends are similar to those shown in previous studies. Data collection is ongoing for the 12+ cohort, with recruitment of the 6+ anticipated over the coming months.

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