2017. ENCORE-CD

Observational/ IFX/ CD / Safety

Five-year Safety Data From ENCORE, a European Observational Safety Registry for Adults With CD Treated With Infliximab [Remicade®] or Conventional Therapy

Long term safety data of CD´s patients on IFX vs conventional treatment. 5 year follow-up.

Results:

- IFX vs CT was associated with serious infections, HR=1.64 [1.17-2.31]
- IFX vs CT was associated with haematological conditions, HR=2.91 [1.51-5.59] and not with lymphoproliferative disorders/malignancy or death.
- Prednisone use related to higher mortality HR=3.58 [1.49-8.61]
- Exposure-adjusted regression, IFX related to lower mortality RR0.39[0.17-0.88]

*CT (Conventional Treatment)

Conclusions:

Infliximab exposure related to increased risk of infections and haematological conditions, whereas mortality may be decreased.

Table 4. Incidence of treatment-emergent adverse events [AEs] by 90-day rule or total exposure.

AE category[a]	Exposure to infliximab: total PYs per 90-day rule = 3687; total PYs per[c] = 7362			Non-exposure to infliximab: total PYs per 90-day rule = 7452; total PYs per[c] = 3776			Exposure vs non-exposure comparison of rates: p-value[d]
	Event number	Incidence rate/1000 patient-years [95% CI]		Event number	Incidence rate/1000 patient-years [95% CI]		
Serious infections[b]	98	26.6	[21.6, 32.4]	129	17.3	[14.5, 20.6]	0.0008
with AZA/6-MP[c]	86	25.4	[20.4, 31.4]	119	17.7	[14.6, 21.1]	
without AZA/6-MP[c]	12	39.1	[20.2, 68.3]	10	14.1	[6.7, 25.9]	
Infusion-related reaction/ hypersensitivity	292	79.2	[70.4, 88.8]	7	0.9	[0.4, 1.9]	Not tested
with AZA/6-MP[c]	262	77.5	[68.4, 87.5]	6	0.9	[0.3, 1.9]	
without AZA/6-MP[c]	30	97.8	[66.0, 139.6]	1	1.4	[0.0, 7.8]	
Congestive heart failure[b]	0	0.0	[0.0, 1.0]	4	0.5	[0.1, 1.4]	Not tested
Haematological condition[b]	46	12.5	[9.1, 16.6]	30	4.0	[2.7, 5.7]	< 0.0001
with AZA/6-MP[c]	45	13.3	[9.7, 17.8]	28	4.2	[2.8, 6.0]	
without AZA/6-MP[c]	1	3.3	0.1, 18.2]	2	2.8	[0.3, 10.2]	
Fatalities[d]	7	1.9	[0.8, 3.9]	41	5.5	[3.9, 7.5]	0.0230
with AZA/6-MP[c]	4	1.2	[0.3, 3.0]	35	5.2	[3.6, 7.2]	
without AZA/6-MP[c]	3	9.8	[2.0, 28.6]	6	8.4	[3.1, 18.4]	
Demyelinating neurological disorder[c]	4	0.5	[0.1, 1.4]	1	0.3	[0.0, 1.5]	0.6121
Lymphoproliferative disorders and Malignancies[c]	56	7.6	[5.7, 9.9]	22	5.8	[3.7, 8.8]	0.1820
with AZA/6-MP[c]	47	7.0	[5.1, 9.3]	20	5.9	[3.6, 9.1]	
without AZA/6-MP[c]	9	14.5	[6.6, 27.5]	2	5.0	[0.6, 18.2]	

Table 5. Treatment and baseline risk factor Cox analysis for predefined safety events.

Events	Event			
	Serious infection	Haematological condition	Lymphoproliferative disorders and malignancy	Fatality
	p-Value, hazard ratio [95% confidence interval]			
Treatment [infliximab vs standard]	p = 0.005 1.64 [1.17–2.31]	p = 0.001 2.91 [1.51–5.59]	p = 0.163 1.44 [0.86–2.42]	p = 0.558 1.22 [0.63–2.36]
Age [continuous]		p = 0.0075 1.02 [1.01–1.04]	p < 0.0001 1.05 [1.03–1.06]	p < 0.0001 1.08 [1.06–1.10]
Draining fistula 4 weeks prior [yes vs no]	p = 0.129 1.31 [0.93–1.86]			p = 0.011 2.45 [1.23–4.87]
Current/ex-smoker	p = 0.064 1.34 [0.98–1.83]	p = 0.001 0.40 [0.24–0.68]		
Disease severity [HB score ≥ 8 vs < 8]				p = 0.132 [1.61 [0.87–3.01]
Disease duration [≥ 6 vs < 6 years]	p = 0.072 1.32 [0.98–1.77]		p = 0.007 2.09 [1.22–3.56]	
Prednisone use in prior 6 months or during study [yes vs no]				p = 0.004 3.58 [1.49–8.61]

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