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Supplement: Safety of Anti-Osteoarthritis Medications

Recommendations for the reporting of harms in manuscripts on clinical trials assessing osteoarthritis drugs: A consensus statement from the European Society for Clinical and Economic Aspects of Osteoporosis, Osteoarthritis and Musculoskeletal Diseases (ESCEO)

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ELECTRONIC SUPPLEMENTARY MATERIAL 1

Table 1: Treatment-emergent adverse events and biological adverse effects in all the intention-to-treat population (safety population) in a two-arm randomized controlled trial

	Drug (n)	**Placebo (n)**		**Drug (n)**	**Placebo (n)**
System organ class 1	f (%)	f (%)	**System organ class 2**	f (%)	f (%)
Event 1	f (%)	f (%)	Event 1	f (%)	f (%)
Event 2	f (%)	f (%)	Event 2	f (%)	f (%)
Event 3	f (%)	f (%)	Event 3	f (%)	f (%)
Event 4	f (%)	f (%)	Event 4	f (%)	f (%)
Event 5	f (%)	f (%)	Event 5	f (%)	f (%)
System organ class 3	f (%)	f (%)	**System organ class 4**	f (%)	f (%)
Event 1	f (%)	f (%)	Event 1	f (%)	f (%)
Event 2	f (%)	f (%)	Event 2	f (%)	f (%)
Event 3	f (%)	f (%)	Event 3	f (%)	f (%)
Event 4	f (%)	f (%)	Event 4	f (%)	f (%)
Event 5	f (%)	f (%)	Event 5	f (%)	f (%)
System organ class 5	f (%)	f (%)	**System organ class 6**	f (%)	f (%)
Event 1	f (%)	f (%)	Event 1	f (%)	f (%)
Event 2	f (%)	f (%)	Event 2	f (%)	f (%)
Event 3	f (%)	f (%)	Event 3	f (%)	f (%)
Event 4	f (%)	f (%)	Event 4	f (%)	f (%)
Event 5	f (%)	f (%)	Event 5	f (%)	f (%)
System organ class 7	f (%)	f (%)	**System organ class 8**	f (%)	f (%)
Event 1	f (%)	f (%)	Event 1	f (%)	f (%)
Event 2	f (%)	f (%)	Event 2	f (%)	f (%)
Event 3	f (%)	f (%)	Event 3	f (%)	f (%)
Event 4	f (%)	f (%)	Event 4	f (%)	f (%)
Event 5	f (%)	f (%)	Event 5	f (%)	f (%)
System organ class 9	f (%)	f (%)	**System organ class 10**	f (%)	f (%)
Event 1	f (%)	f (%)	Event 1	f (%)	f (%)
Event 2	f (%)	f (%)	Event 2	f (%)	f (%)
Event 3	f (%)	f (%)	Event 3	f (%)	f (%)
Event 4	f (%)	f (%)	Event 4	f (%)	f (%)
Event 5	f (%)	f (%)	Event 5		
Severe adverse events	f (%)	f (%)	**Serious adverse events**	f (%)	f (%)
Event 1	f (%)	f (%)	Event 1	f (%)	f (%)
Event 2	f (%)	f (%)	Event 2	f (%)	f (%)
Event 3	f (%)	f (%)	Event 3	f (%)	f (%)
Event 4	f (%)	f (%)			
Event 5	f (%)	f (%)			
Withdrawals due to adverse events	f (%)	f (%)	**Any adverse event**	f (%)	f (%)
Event 1	f (%)	f (%)	Event 1	f (%)	f (%)
Event 2	f (%)	f (%)	Event 2	f (%)	f (%)
Event 3	f (%)	f (%)	Event 3	f (%)	f (%)
Event 4	f (%)	f (%)	Event 4	f (%)	f (%)
Event 5	f (%)	f (%)	Event 5	f (%)	f (%)
Other clinically relevant AEs	-	-			
Event 1	f (%)	f (%)			
Event 2	f (%)	f (%)			
Event 3	f (%)	f (%)			
Biological parameters	-	-	**Biological parameters** (continued)	-	-
Blood glucose	a (%)	a (%)	Red blood cells	a (%)	a (%)
Serum level of urea	a (%)	a (%)	White blood cells	a (%)	a (%)
Serum level of creatinine	a (%)	a (%)	Platelets	a (%)	a (%)
AST	a (%)	a (%)	Haemoglobin	a (%)	a (%)
ALT	a (%)	a (%)			

n = number of patients analysed (ITT population);
f = number of participants who experienced the event at least once during the trial;
a = number of patients with abnormal change in the parameter at all timepoints, from baseline to end of treatment

Table 2: Treatment-emergent adverse events and biological adverse effects in the intention-to-treat population (safety population) in a multiple arm randomized controlled trial

	Intervention A (n)	**Intervention B (n)**	**Intervention C (n)**	**Placebo (n)**
System organ class 1	f (%)	f (%)	f (%)	f (%)
Event 1	f (%)	f (%)	f (%)	f (%)
Event 2	f (%)	f (%)	f (%)	f (%)
Event 3	f (%)	f (%)	f (%)	f (%)
Event 4	f (%)	f (%)	f (%)	f (%)
Event 5	f (%)	f (%)	f (%)	f (%)
System organ class 2	f (%)	f (%)	f (%)	f (%)
Event 1	f (%)	f (%)	f (%)	f (%)
Event 2	f (%)	f (%)	f (%)	f (%)
Event 3	f (%)	f (%)	f (%)	f (%)
Event 4	f (%)	f (%)	f (%)	f (%)
Event 5	f (%)	f (%)	f (%)	f (%)
System organ class 3	f (%)	f (%)	f (%)	f (%)
Event 1	f (%)	f (%)	f (%)	f (%)
Event 2	f (%)	f (%)	f (%)	f (%)
Event 3	f (%)	f (%)	f (%)	f (%)
Event 4	f (%)	f (%)	f (%)	f (%)
Event 5	f (%)	f (%)	f (%)	f (%)
System organ class 4	f (%)	f (%)	f (%)	f (%)
Event 1	f (%)	f (%)	f (%)	f (%)
Event 2	f (%)	f (%)	f (%)	f (%)
Event 3	f (%)	f (%)	f (%)	f (%)
Event 4	f (%)	f (%)	f (%)	f (%)
Event 5	f (%)	f (%)	f (%)	f (%)
System organ class 5	f (%)	f (%)	f (%)	f (%)
Event 1	f (%)	f (%)	f (%)	f (%)
Event 2	f (%)	f (%)	f (%)	f (%)
Event 3	f (%)	f (%)	f (%)	f (%)
Event 4	f (%)	f (%)	f (%)	f (%)
Event 5	f (%)	f (%)	f (%)	f (%)
System organ class 6	f (%)	f (%)	f (%)	f (%)
Event 1	f (%)	f (%)	f (%)	f (%)
Event 2	f (%)	f (%)	f (%)	f (%)
Event 3	f (%)	f (%)	f (%)	f (%)
Event 4	f (%)	f (%)	f (%)	f (%)
Event 5	f (%)	f (%)	f (%)	f (%)
System organ class 7	f (%)	f (%)	f (%)	f (%)
Event 1	f (%)	f (%)	f (%)	f (%)
Event 2	f (%)	f (%)	f (%)	f (%)
Event 3	f (%)	f (%)	f (%)	f (%)
Event 4	f (%)	f (%)	f (%)	f (%)
Event 5	f (%)	f (%)	f (%)	f (%)
System organ class 8	f (%)	f (%)	f (%)	f (%)
Event 1	f (%)	f (%)	f (%)	f (%)
Event 2	f (%)	f (%)	f (%)	f (%)
Event 3	f (%)	f (%)	f (%)	f (%)
Event 4	f (%)	f (%)	f (%)	f (%)
Event 5	f (%)	f (%)	f (%)	f (%)
System organ class 9	f (%)	f (%)	f (%)	f (%)
Event 1	f (%)	f (%)	f (%)	f (%)
Event 2	f (%)	f (%)	f (%)	f (%)
Event 3	f (%)	f (%)	f (%)	f (%)
Event 4	f (%)	f (%)	f (%)	f (%)
Event 5	f (%)	f (%)	f (%)	f (%)

	Intervention A (n)	**Intervention B (n)**	**Intervention C (n)**	**Placebo (n)**
System organ class 10	f (%)	f (%)	f (%)	f (%)
Event 1	f (%)	f (%)	f (%)	f (%)
Event 2	f (%)	f (%)	f (%)	f (%)
Event 3	f (%)	f (%)	f (%)	f (%)
Event 4	f (%)	f (%)	f (%)	f (%)
Event 5	f (%)	f (%)	f (%)	f (%)
Severe adverse events	f (%)	f (%)	f (%)	f (%)
Event 1	f (%)	f (%)	f (%)	f (%)
Event 2	f (%)	f (%)	f (%)	f (%)
Event 3	f (%)	f (%)	f (%)	f (%)
Event 4	f (%)	f (%)	f (%)	f (%)
Event 5	f (%)	f (%)	f (%)	f (%)
Serious adverse events	f (%)	f (%)	f (%)	f (%)
Event 1	f (%)	f (%)	f (%)	f (%)
Event 2	f (%)	f (%)	f (%)	f (%)
Event 3	f (%)	f (%)	f (%)	f (%)
Event 4	f (%)	f (%)	f (%)	f (%)
Event 5	f (%)	f (%)	f (%)	f (%)
Event 6	f (%)	f (%)	f (%)	f (%)
Event 7	f (%)	f (%)	f (%)	f (%)
Withdrawals due to adverse events	f (%)	f (%)	f (%)	f (%)
Event 1	f (%)	f (%)	f (%)	f (%)
Event 2	f (%)	f (%)	f (%)	f (%)
Event 3	f (%)	f (%)	f (%)	f (%)
Event 4	f (%)	f (%)	f (%)	f (%)
Event 5	f (%)	f (%)	f (%)	f (%)
Any adverse event	f (%)	f (%)	f (%)	f (%)
Event 1	f (%)	f (%)	f (%)	f (%)
Event 2	f (%)	f (%)	f (%)	f (%)
Event 3	f (%)	f (%)	f (%)	f (%)
Event 4	f (%)	f (%)	f (%)	f (%)
Event 5	f (%)	f (%)	f (%)	f (%)
Other clinically relevant adverse events	-	-	-	-
Event 1	f (%)	f (%)	f (%)	f (%)
Event 2	f (%)	f (%)	f (%)	f (%)
Event 3	f (%)	f (%)	f (%)	f (%)
Biochemical and other biological parameters	-	-	-	-
Blood glucose	a (%)	a (%)	a (%)	a (%)
Serum level of urea	a (%)	a (%)	a (%)	a (%)
Serum level of creatinine	a (%)	a (%)	a (%)	a (%)
AST	a (%)	a (%)	a (%)	a (%)
ALT	a (%)	a (%)	a (%)	a (%)
Red blood cells	a (%)	a (%)	a (%)	a (%)
White blood cells	a (%)	a (%)	a (%)	a (%)
Platelets	a (%)	a (%)	a (%)	a (%)
Haemoglobin	a (%)	a (%)	a (%)	a (%)

n = number of patients analysed (ITT population);
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