

Serious and adverse events by body system and intervention group

Body system	Proof of principle phase (0-6 months)						Exploratory phase (6-12 months)							
	Tapered 33%, n = 15 (96 episodes)		Tapered 66%, n = 13 (71 episodes)		Controls, n = 19 (120 episodes)		Tapering 33% until stop, n = 9 (54 episodes)		Tapering 66% until stop, n = 4 (28 episodes)		Re-randomized control group to			
											Tapered 33%, n = 10 (43 episodes)		Tapered 66%, n = 6 (35 episodes)	
	Serious	All	Serious	All	Serious	All	Serious	All	Serious	All	Serious	All	Serious	All
Cardiovascular		3		1		3		0		0		2		0
Digestive		13		3		12		2		0		6		7
ENT		5		1		5		4		2		5		7
Endocrine/metabolic		0		0		0		0		0		0		0
Genitourinary	1	1		2		3		0		0		2		0
Haematological		0	1	1		6		1		0		0		0
Mental		0		0		1		0		2		0		5
Musculoskeletal		51		37		36		45		18		19		14
Nervous system		4		1		4		0		0		0		0
Ophthalmological		0		0		4		0		0		0		1
Respiratory		8		8		33		2		1		8		7
Skin	1	11		0		13		0		5		0	1	0

Seventy-six patients had an adverse event; of those, 47 patients had an AE in the first 6 months and 29 in the next 6 months.