

Table I. Study and patient characteristics of included studies

Study	Study design – Country	Study duration	Sample size, n	Sex (female, %)	Age, years Mean (SD) [range]	Duration of spasticity, years Mean (SD) [range]	Severity of spasticity	Baclofen dosage (mg/day)
<i>Baclofen vs placebo</i>								
Multiple sclerosis								
Hudson & Weightman, 1971 (31)	Crossover – UK	10 days	23	30.4	30–63	—	Severe	30
Duncan et al., 1976 (25)	Crossover – USA	4 weeks	25	50	36.4	—	—	15–100
Sachais et al., 1977 (30)	Parallel – USA	BAC PLA	85 81	57.4 61.5	43 [20–64] 43 [21–65]	10.6 [7 months–31] 11.2 [8 months–29]	—	Outpatients 15–80 Inpatients 30–80
Feldman et al., 1978 (26)	Crossover – USA	10 weeks	33	—	43 [38–53]	15.3 [3–30]	—	15–80
Sawa & Paty, 1979 (27)	Crossover – Canada	21 days	21	76.3	24–54	12.6 [est.]	—	15–60
Brar et al., 1991 (32)	Crossover – USA	10 weeks	38	76.3	24–54	—	Mild-to-moderate	15–20
Ørsnes et al., 2000 (46)	Crossover – Denmark	11 days	14	64.3	43.4 (9.1)	—	Moderate	15–45
Cerebral palsy								
Milla & Jackson, 1977 (28)	RCT-crossover – UK	4 weeks	20	55	2–16	—	Moderate	10–60 (30–40 for children 2–7 years)
McKinley et al., 1980 (33)	RCT-crossover – UK	4 weeks	20	50	7–16	—	—	0.5 mg/kg/day – 60 mg/day
Stroke								
Medaer et al., 1991 (29)	RCT-crossover – Belgium	4 weeks	20	65	64.9 (16.4)	4 [1 months–13 years]	Severe	10–50
<i>Baclofen vs active comparators or open-label</i>								
Multiple sclerosis								
Baclofen vs tizanidine								
Smolenski et al., 1981 (34)	Parallel – Switzerland	BAC TIZ	6 weeks	10 11	50 55	55.0 (10.0) [42–73] 53.0 (11.0) [40–69]	26.6 (8.0) 17.3 (10.0)	Moderate-to-severe 10–80
Newman et al., 1982 (35)	Crossover – UK	BAC	1 month	36	53.8	45.9 (9.4)	9.0 (9.9)	Moderate-to-severe 5–40
Stien et al., 1987 (36)	Parallel – Norway	TIZ	6 weeks	21 19	60 50	45 ^a [26–66] 50 ^a [29–70]	13 ^a [5–33] 14 ^a [4–39]	Moderate-to-severe 10–90
Bass et al., 1988 (44)	Crossover – Canada	BAC	5 weeks	62	49.9	51.0 [est.]	8.1 [est.]	Moderate Moderate-to-severe 5–80
Eyssette et al., 1988 (37)	Parallel – France	TIZ	8 weeks	50 50	42 44.0	47.5 (1.7) 46.8 (1.6)	—	— 16–60
Hoogstraten et al., 1988 (38)	Crossover – Holland	BAC	4 weeks	16	37.5	54.9 (8.3) [34–67]	—	Moderate 15–60
Baclofen vs diazepam								
Cartlidge et al., 1974 (45)	Crossover – UK	BAC	4 weeks	40	47.5	22–61	—	Moderate 30–60
From & Hudson, 1975 (43)	Crossover – Denmark	BAC	4 weeks	17	62.9	51 [38–68]	—	Moderate 30–120
Spinal cord injury								
Jones & Lance, 1976 (23)	Open-label – Australia	— BAC	6 years	113 33	25.7 0	35 [6–68]	—	— 30–200
Nance et al., 1994 (39)	Comparative (crossover) – Canada	CLO CYP	3 weeks	—	—	—	—	Moderate-to-severe Up to 80
Aydin et al., 2005 (40)	Comparative – Turkey	BAC TENS	8 weeks	10 11	100 45.5	32.7 (16.3) 29.3 (7.3)	11.5 (11.7) [4–44] 11.5 (13.9) [2–49]	Moderate-to-severe 5–80
Cerebral palsy								
Bresolin et al., 2009 (41)	RCT-parallel – Italy	BAC EPE	8 weeks	40 40	40 37.5	52.4 (15.1) 49.8 (13.8)	93.7 (90.9) month 111.6 (99.3) month	Moderate-to-severe 30–60
Brain injury								
Medici et al., 1989 (42)	RCT-parallel – Uruguay	BAC TIZ	1 years	15 15	13.3 26.7	49 [24–68] 50 [22–73]	4.5 [0.5–14] 2.5 [0.1–10]	Moderate-to-severe 20–50
Meythaler et al., 2004 (24)	Open-label – US	— PLA	3 months	35	37.1	31 [6–86]	—	Severe 5–80

^aMedian.

BAC: baclofen; CLO: clonidine; CYP: cyproheptadine; EPE: eperisone; TENS: transcutaneous electrical nerve stimulation; TIZ: tizanidine; PLA: placebo.