

Table 13: Clinical evidence profile: Comparison 1: intrathecal baclofen, post-operative versus pre-operative outcomes

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Intrathecal baclofen	Pre-operative	Relative (95% CI)	Absolute		
Walking (follow-up 4 years; assessed with: household or community ambulation)												
1	observational studies	no serious risk of bias	no serious inconsistency	no serious indirectness	serious ¹	none	18/24 (75%)	15/24 (62.5%)	RR 1.2 (0.82 to 1.77)	125 more per 1000 (from 113 fewer to 481 more)	VERY LOW	CRITICAL
Gross motor function (follow-up 1 years; measured with: GMFM score; range of scores: 0-100; Better indicated by higher values)												
1	observational studies	no serious risk of bias	no serious inconsistency	no serious indirectness	serious ²	none	9	9	-	MD 2.34 higher (2.34 lower to 7.02 higher)	VERY LOW	CRITICAL
Tone (ITB 100 micrograms bolus) upper extremity (follow-up 4 hours; measured with: Ashworth scale; range of scores: 1-5; Better indicated by lower values)												
1	randomised trials	no serious risk of bias	no serious inconsistency	serious ³	serious ⁴	none	8	8	-	MD 0.23 lower (0.71 lower to 0.25 higher)	LOW	CRITICAL

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Intrathecal baclofen	Pre-operative	Relative (95% CI)	Absolute		
Tone (ITB 100 micrograms bolus) lower extremity (follow-up 4 hours; measured with: Ashworth scale; range of scores: 1-5; Better indicated by lower values)												
1	randomised trials	no serious risk of bias	no serious inconsistency	serious ³	serious ²	none	8	8	-	MD 1.4 lower (2.44 to 0.36 lower)	LOW	CRITICAL
Tone (ITB pump) lower extremity (follow-up 1 to 5 years; measured with: Ashworth scale; range of scores: 1-5; Better indicated by lower values)												
2	observational studies	no serious risk of bias	no serious inconsistency	serious ⁵	serious ²	none	38	38	-	MD ranged from 1.9 to 1.16 lower	VERY LOW	CRITICAL
Tone (ITB pump) upper extremity (follow-up 1 years; measured with: Ashworth scale; range of scores: 1-5; Better indicated by lower values)												
1	observational studies	no serious risk of bias	no serious inconsistency	no serious indirectness	serious ²	none	13	13	-	MD 1.3 lower (2.15 to 0.45 lower)	VERY LOW	CRITICAL
Health related quality of life - not reported												
-	-	-	-	-	-	-	-	-	-	-		CRITICAL
Pain - not reported												
-	-	-	-	-	-	-	-	-	-	-		IMPORTANT
Adverse events (ITB continuous infusion) (follow-up 4 to 5 years; assessed with: catheter or pump infections)												
2	observational studies	serious ¹	no serious inconsistency	no serious indirectness	serious ⁴	none	Rate ranged from 4.2 to 8%				VERY LOW	IMPORTANT
Adverse events (ITB continuous infusion) (follow-up 4 to 5 years; assessed with: catheter disconnection / breakage)												

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Intrathecal baclofen	Pre-operative	Relative (95% CI)	Absolute		
3	observational studies	serious ¹	no serious inconsistency	no serious indirectness	serious ⁴	none	Rate ranged from 4.2% to 17%				VERY LOW	IMPORTANT
Adverse events (ITB continuous infusion) (assessed with: Constipation)												
2	observational studies	serious ¹	no serious inconsistency	no serious indirectness	serious ⁴	none	Rate ranged from 4% to 15%				VERY LOW	IMPORTANT
Adverse events (ITB continuous infusion) (follow-up 1 to 5 years; assessed with: Anxiety and depression)												
1	observational studies	serious ¹	no serious inconsistency	no serious indirectness	serious ⁴	none	Rate was 8%				VERY LOW	IMPORTANT
Adverse events (ITB continuous infusion) (follow-up 1 years; assessed with: Seizures)												
1	observational studies	serious ¹	no serious inconsistency	no serious indirectness	serious ⁴	none	Rate was 15%				VERY LOW	IMPORTANT
Satisfaction - not reported												
-	-	-	-	-	-	-	-	-	-	-		IMPORTANT
Concurrent medications - not reported												
-	-	-	-	-	-	-	-	-	-	-		IMPORTANT

CI: confidence interval; GMFM: Gross Motor Function Measure; HRQoL: Health related quality of life; ITB: intrathecal baclofen; MD: mean difference; MID: minimally important difference; RR: risk ratio

1 No comparator

2 Confidence interval includes one default MID threshold

3 Intrathecal bolus injection rather than implanted pump

4 Number of participants <400

5 Extremity not reported in one of the studies