

<b>Author Year</b> <b>Country</b> <b>Research Design</b> <b>PEDro</b> <b>Sample Size</b>	<b>Methods</b>	<b>Outcomes</b>
<p> <a href="#">Geisler et al.</a> (2001)  <a href="#">Geisler et al.</a> (2001)  <a href="#">Geisler et al.</a> (2001)            USA            RCT            PEDro=8            N=760         </p>	<p> <b>Population:</b> Age range=17-69 yr; Gender: male=80%, female=20%; Level of injury: cervical-thoracic; Severity of injury: complete=63.4%, incomplete=36.6%.  <b>Treatment:</b> Patients were randomly assigned to receive either low dose monosialotetrahexosylganglioside (GM-1) ganglioside (Sygen®; 300 mg loading dose, followed by 100 mg/day for 56 days), high dose Sygen® (600 mg loading dose followed by 200 mg/day for 56 days), or placebo within 72 hr of injury. Treatments were administered through a gastric nasal tube. All patients initially received methylprednisolone sodium succinate (MPSS) according to National Acute Spinal Cord Injury Study (NASCIS) II guidelines for the first 24 hr before receiving Sygen® treatment.  <b>Outcome Measures:</b> The following at 6 months: neurological recovery using the AIS and the modified Benzel Classification scale, ASIA motor function, ASIA sensory function (pinprick and light touch), bowel and bladder function, sacral sensation, anal contraction, mortality, adverse event outcomes.  <b>Chronicity:</b> Mean time from injury to study treatment was 55.6 hr, 54 hr and 54.4 hr for Sygen® 100 mg, Sygen® 200 mg and placebo groups, respectively.         </p>	<ol style="list-style-type: none"> <li>1. Overall, there were no significant differences in neurological recovery (both motor and sensory) between Sygen® groups or the placebo (p&gt;0.05).</li> <li>2. Neurological recovery according to the Modified Benzel Classification scale occurred faster in patients receiving Sygen® (p&lt;0.0128), but patients who received placebo reached the same level of improvement by 26 weeks. Also, patients who received Sygen® experienced a faster recovery of ASIA motor and sensory functions, but patients who received placebo reached the same degree of function.</li> <li>3. There were trends for patients receiving Sygen® to show improved bowel and bladder function, sacral sensation, and anal contraction compared to patients who received the placebo, but these were not significant (p&lt;0.05).</li> <li>4. There were no significant differences in mortality between patients who received low dose Sygen®, high dose Sygen®, or placebo (p&gt;0.05). Patients with complete injuries had a significantly higher mortality rate than patients with incomplete injuries (p=0.017).</li> <li>5. There were no significant differences in adverse event outcomes between patients who received Sygen® and patients who received placebo (p&gt;0.05).</li> </ol>
<p> <a href="#">Geisler et al.</a> 1990  <a href="#">Geisler et al.</a> 1991            USA            RCT            PEDro=9            N<sub>initial</sub>=37, N<sub>final</sub>=34         </p>	<p> <b>Population:</b> Age range=18-71 yr; Gender: not specified; Level of injury: cervical-thoracic; Severity of injury: complete=29%, incomplete=71%.  <b>Treatment:</b> Patients were randomly assigned to receive either monosialotetrahexosylganglioside (GM-1) ganglioside (GM-1 group; 100 mg/day) or placebo within 72 hr of injury. Amount of doses varied per patient. All patients received 250 mg methylprednisolone (MP) on admission followed by 125 mg MP every 6 hr for 72 hr.  <b>Outcome Measures:</b> The following after one year: neurological recovery based on Frankel grades, ASIA motor function, adverse event outcomes, death.         </p>	<ol style="list-style-type: none"> <li>1. Patients who received GM-1 ganglioside improved in the form of at least 1 Frankel grade significantly more (p=0.034) than patients who received placebo. Significantly more patients who received GM-1 ganglioside were able to improve 2 or more grades compared to patients who received placebo (p=0.033).</li> <li>2. Patients who received GM-1 ganglioside experienced significantly more neurological recovery in the form of ASIA grade improvements compared to patients who received placebo</li> </ol>

	<p><b>Chronicity:</b> Mean time from injury to study entry was 48.2 hr and 51 hr for the GM-1 group and placebo group, respectively.</p>	<p>(p=0.043).</p> <ol style="list-style-type: none"><li>3. Significantly more patients who received GM-1 ganglioside were able to recover from 'paralyzed' to 'useful power' muscle grades on the ASIA motor scale compared to patients who received placebo (p=0.039). The authors noted that the improvement was due to the patients regaining useful function in paralyzed muscles rather than to paretic muscles improving in strength.</li><li>4. No patients in the trial died and there were no significant differences in adverse event outcomes between the two groups (p&gt;0.05).</li></ol>
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