# *Autologous olfactory ensheathing cell transplantation in human spinal cord injury*

*F. Féron, C. Perry, J. Cochrane, P. Licina, A. Nowitzke, S. Urquhart, T. Geraghty, A. Mackay-Sim*
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## Summary

Olfactory ensheathing cells transplanted into the injured spinal cord in animals promote regeneration and remyelination of descending motor pathways through the site of injury and the return of motor functions. In a single-blind, Phase I clinical trial, we aimed to test the feasibility and safety of transplantation of autologous olfactory ensheathing cells into the injured spinal cord in human paraplegia. Participants were three male paraplegics, 18–55 years of age, with stable, complete thoracic injuries 6–32 months previously, with stable spinal column, no implanted prostheses, and no syrinx. Olfactory ensheathing cells were grown and purified *in vitro* from nasal biopsies and injected into the region of damaged spinal cord. The trial design includes a matched injury group as a control for the assessors, who are blind to treatment status. Assessments, made before transplantation and at regular intervals subsequently, include MRI, medical, neurological and psychosocial assessments, and standard American Spinal Injury Association and Functional Independence Measure assessments. One year after cell implantation, there were no medical, surgical or other complications to indicate that the procedure is unsafe. There is no evidence of spinal cord damage nor of cyst, syrinx or tumour formation. There was no neuropathic pain reported by the participants, no change in psychosocial status and no evidence of deterioration in neurological status. Participants will be followed for 3 years to confirm long-term safety and to compare neurological, functional and psychosocial outcomes with the control group. We conclude transplantation of autologous olfactory ensheathing cells into the injured spinal cord is feasible and is safe up to one year post-implantation.

- human
- transplantation
- spinal cord injury
- paraplegia

- ASIA = American Spinal Injury Association
- GFAP = glial fibrillary acidic protein

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