Safety and clinical effects of NTECELL® (immunoprotected [alaginate-encapsulated] porcine choroid plexus cells for xenotransplantation) in patients with Parkinson's disease (PD): 26 weeks follow-up

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Introduction

Centrophenolic (CSF) contains a variety of neurotransmitters and neuroprotective factors that play critical roles in maintaining the health of the brain. Our pre-clinical studies with NTECELL demonstrated that CSF could result in restoration of degenerated neural functions, thereby supporting the application of NTECELL as a disease-modifying cell-based therapy for neurodegenerative conditions.

We conducted a Phase I/II clinical study at Auckland City Hospital, Auckland, New Zealand in four patients with Parkinson's disease (PD) to assess the safety and clinical effects of NTECELL implanted into the putamen, which is currently the front-line treatment for PD patients.

Background

NTECELL comprises of renewed porcine choroid plexus cells encapsulated in alginate microcapsules. The Auckland Island, which was the source of the choanal tissue, was screened and for pathogens. NTECELL is effectively a novel cell therapy platform based on the choroid plexus, a highly vascularised region of the brain that produces multiple neurotransmitters.

Our pre-clinical studies with NTECELL allocated the storage of both CSF and NTECELL in patients with Parkinson’s disease to enhance the health of the brain. Our pre-clinical studies with NTECELL demonstrated that CSF could result in restoration of degenerated neural functions, thereby supporting the application of NTECELL as a disease-modifying cell-based therapy for neurodegenerative conditions.

Methods

Our clinical trial was approved by the Ministry of Health and conducted at the Auckland City Hospital (Auckland, New Zealand) in accordance with the Declaration of Helsinki and Good Clinical Practice (GCP). An extensive and updated informed consent procedure was completed by all patients prior to participating in this trial.

The trial was conducted in accordance with the Australian guidelines specified for PD. We implanted 40 NTECELL microcapsules (approx. 40,000 choroid plexus cells for xenotransplantation) in patients with Parkinson's disease (PD): in order to assess the safety and clinical effects of NTECELL implanted into the putamen, the following timeframe up to 26 weeks post-implant.

Results

Patient demographics

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Discussion

The primary endpoint of this clinical trial was to determine the safety and clinical effects of NTECELL implantation in patients with PD. All adverse events were recorded and the investigator assessed each event attributable to the implant.

Conclusion

NTCELL implantation was safe and well tolerated. The primary endpoint of this clinical trial was to determine the safety and clinical effects of NTECELL implantation in patients with PD. All adverse events were recorded and the investigator assessed each event attributable to the implant.

The marked improvement immediately after the procedure could relate to a lesion effect. The improvement at this time would be consistent with the notion that NTECELL implantation would have considerable potential in the treatment of Parkinson's disease.

The safety monitoring board (DSMB) confirmed the investigator's recommendation that none of the four patients would require an increase in dosage of PD. The DSMB recommended that the investigators continue to monitor the patients for at least 26 weeks after implantation.

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