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Safety and feasibility of neural transplantation in early to moderate Huntington's disease in the UK

Submission date	Recruitment status	[ ] Prospectively registered
23/10/2000	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
23/10/2000	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
27/08/2019	Mental and Behavioural Disorders	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
G9825903 and 071659

Study information

Scientific Title
Safety and feasibility of neural transplantation in early to moderate Huntington's disease in the UK

Study objectives
To determine the safety, feasibility and efficacy of foetal tissue transplantation as a restorative therapy for Huntington's disease

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Primary study design
Interventional

Study design
Multicentre, randomised controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Neuroscience, psychiatry

Interventions
Patients in matched pairs randomly allocated to experimental and control conditions; the pairs are selected from a larger research cohort undergoing longitudinal assessment but not (yet) selected for participation in the surgical trial.

All subjects will be examined using Positron Emission Tomography (PET) to assess survival and functional integration of the implanted grafts. The imaging component of the study, entitled 'Pre- and post-operative PET studies of Huntington's disease patients receiving human fetal striatal cell implants' (RTF - 071659), is funded by Wellcome trust, as part of the research training fellowship (for Y F Tai).

As of September 2007, this trial is still open, but temporarily suspended following introduction of EU Tissue directive and pending upgrading of facilities to GMP compliance and MHRA accreditation.

The end date of the follow up period will be extended to two years after thelast patient was operated on.

Please also note that as of 22nd January 2007 the Sponsor institution of this trial changed. The previous sponsor was:
Cardiff University (UK)
Cardiff
CF10 3XQ

United Kingdom
+44 (0)29 2087 4000
Http://www.cardiff.ac.uk

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
Safety trial:
1. Presence/absence of adverse events
2. Feasibility:
a. co-ordination of an effective and efficient programme for foetal tissue collection
b. biosafety assessment
c. preparation and implantation into identified patients and their long term evaluation on the relevant structural and functional criteria of graft survival and efficacy

Efficacy trial:
Retardation or reversal of the progress of the disease in the affected patients as determined by the neurological, neuropsychological and neuropsychiatric and imaging criteria of neuropsychological tests of cognition using the CAmbridge Neuropsychological Test Automated Battery (CANTAB) test battery.

Key secondary outcome(s)
No secondary outcome measures

Completion date
30/06/2008

Reason abandoned (if study stopped)
This trial is still open, but temporarily suspended following introduction of EU Tissue directive and pending upgrading of facilities to GMP compliance and MHRA accreditation

Eligibility

Key inclusion criteria
1. Genetically confirmed Huntington's disease
2. Early to moderate stage of disease
3. Presence of motor signs
4. Availability of one close primary informant

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group

Adult

Sex
Not Specified

Total final enrolment
17

Key exclusion criteria
1. Advanced disease
2. Still employable in usual occupation
3. Other concurrent major illness
4. Current serious psychiatric disturbance
5. Inadequate social support
6. Below the age of 18

Date of first enrolment
01/10/1999

Date of final enrolment
30/06/2008

Locations

Countries of recruitment
United Kingdom

Wales

Study participating centre
The Brain Repair Group
Cardiff
United Kingdom
CF10 3US

Sponsor information

Organisation
Medical Research Council (UK)

Funder(s)

Funder type

Charity

Funder Name
The Wellcome Trust (UK) (grant ref: 071659)

Funder Name
Medical Research Council (UK) (grant ref: G9825903)

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, Medical Research Committee and Advisory Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/12/2002		Yes	No
Results article	results	01/06/2013		Yes	No
Results article	results	01/12/2018	27/08/2019	Yes	No