

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

Submission date 23/10/2000	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 23/10/2000	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 27/08/2019	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

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

Study design

Multicentre, randomised controlled trial

Primary study design

Interventional

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 the last 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](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