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What is the clinical effect and cost effectiveness of treating upper limb spasticity due to stroke with botulinum toxin?

Submission date 06/08/2004	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 06/08/2004	**Overall study status** Completed	
Last Edited 07/12/2010	**Condition category** Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

HTA 02/41/06

Study information

Scientific Title

Study objectives
Objective: To compare the upper limb (UL) function of patients with spasticity due to stroke who receive botulinum toxin injection(s) to the upper arm plus a four week evidence based UL therapy programme (intervention group) with patients who receive the UL therapy programme alone (control group) at 1 month after study entry.

Protocol can be found at http://www.hta.ac.uk/protocols/200200410006.pdf
More details can be found at http://www.hta.ac.uk/1408

Please note that, as of 26/08/2009, the anticipated end date of this trial has been updated from 31/07/2008 to 28/02/2009.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Upper limb spasticity due to stroke

Interventions
Intervention: Botulinum toxin plus upper limb therapy programme
Control: Upper limb therapy programme alone

Intervention Type

Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Botulinum toxin

Primary outcome measure
Action Research Arm Test (ARAT).

Secondary outcome measures
ARAT at 3 and 12 months, Nine Hole Peg Test; biomechanical assessment of spasticity; motor impairment (Motricity Index and grip strength by dynamometer); UL pain (numerical rating scale). Assessment of patient-selected UL goals; disability (Barthel ADL Index); and quality of life (Stroke Impact Scale and EQ-5D).

Overall study start date
01/02/2005

Completion date
28/02/2009

Eligibility

Key inclusion criteria
1. Age over 18 years
2. At least 1 month since stroke
3. Upper limb (UL) spasticity (modified Ashworth scale >2 at the elbow and/or spasticity at wrist or shoulder
4. Reduced UL function but with some general function retained (Action Research Arm Test [ARAT] score 4-56)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
390

Key exclusion criteria

1. Significant speech or cognitive impairment which will impede assessment. Participants must be able to understand and complete assessments (Abbreviated Mental Test Score [AMTS] >5 and Sheffield Aphasia score above age defined cut offs for receptive dysphasia).
2. Other significant upper limb impairment e.g. fracture or frozen shoulder within six months, severe arthritis, amputation
3. Evidence of contracture
4. Female patients who are pregnant or lactating or who are not willing to take adequate precautions against pregnancy for the duration of the study
5. Diagnosis likely to interfere with rehabilitation or outcome assessments e.g. registered blind, malignancy
6. Other diagnosis which may contribute to upper limb spasticity e.g. multiple sclerosis, cerebral palsy
7. Contraindications to intramuscular injection
8. Religious objections to blood products (botulinum toxin contains human albumen)
9. Contraindications to botulinum toxin which include bleeding disorders, myasthenia gravis and concurrent use of aminogycosides
10. Use of botulinum toxin to the upper limb in the previous three months
11. Known allergy or hypersensitivity to any of the test compounds

Date of first enrolment
01/02/2005

Date of final enrolment
28/02/2009

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
School of Population & Health Sciences
Newcastle upon Tyne
United Kingdom
NE2 4HH

Sponsor information

Organisation
The Newcastle Upon Tyne Hospitals NHS Foundation Trust (UK)

Sponsor details

The Newcastle upon Tyne Hospitals NHS Trust
Freeman Hospital
Freeman Road
High Heaton
Newcastle upon Tyne
England
United Kingdom
NE7 7DN

Sponsor type
Hospital/treatment centre

Website
http://www.newcastle-hospitals.org.uk/

ROR
https://ror.org/05p40t847

Funder(s)

Funder type
Industry

Funder Name
NIHR Health Technology Assessment Programme - HTA (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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	01/05/2010		Yes	No