

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	☒ Prospectively registered ☐ Protocol
Registration date 06/08/2004	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 07/12/2010	Condition category Circulatory System	☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr Helen Rodgers

Contact details

School of Population & Health Sciences
University of Newcastle
The Medical School
Newcastle upon Tyne
United Kingdom
NE2 4HH
+44 (0)191 222 6779
helen.rodgers@ncl.ac.uk

Additional identifiers

Protocol serial number

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

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

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(s)

Action Research Arm Test (ARAT).

Key secondary outcome(s)

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).

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

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 aminoglycosides
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

United Kingdom

England

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)

ROR

<https://ror.org/05p40t847>

Funder(s)

Funder type

Industry

Funder Name

NIHR Health Technology Assessment Programme - HTA (UK)

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	01/05/2010		Yes	No