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Is it clinically effective to treat arm flexor spasticity, with Botulinum toxin - type A (BoNTA) and physiotherapy, as soon as signs of abnormal muscle activity are observed?

Submission date
21/10/2011

Recruitment status
No longer recruiting

Registration date
21/10/2011

Overall study status
Completed

Last Edited
12/06/2019

Condition category
Circulatory System

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

Clinical Trials Information System (CTIS)
2010-021257-39

ClinicalTrials.gov (NCT)
NCT01882556

Protocol serial number

10961

Study information

Scientific Title
Is it clinically effective to treat arm flexor spasticity, with Botulinum toxin type A (BoNTA) and physiotherapy, as soon as signs of abnormal muscle activity are observed: a randomised trial

Acronym
EUBoSS (Early Use of Botulinum toxin in post Stroke Spasticity)

Study objectives
Patients who survive a stroke are often left with an arm that cannot be used. One reason for this is that the muscles affected by the stroke become overactive. This is known as spasticity. Such unwanted muscle overactivity, if left untreated or poorly managed, can lead to limb deformities. For example, the wrist and fingers in the arm affected by spasticity become stiff and curl into a fist and the hand cannot be used for any functional purpose. Palm hygiene can become difficult and patients find this deformity unsightly and painful. Botulinum toxin (BT) has been shown to reduce muscle overactivity and is licensed for this purpose. In current practice this treatment is often used as a last line of defence. Although BT can reduce the muscle overactivity, when injected using current protocols, it seems to have little impact on the recovery of function and /or treating the limb deformities and pain. If BT can be given in the early stages of a stroke, i.e. as soon as the muscle overactivity is observed, then we will be able to treat spasticity and may prevent the limb deformities and pain from developing. We may also be able to assist the recovery of arm movement in some of the patients who would otherwise not have regained this. In addition to benefiting the patient, the prevention of secondary complications by early treatment may reduce the costs of long term care to the NHS . We hope to discover if our plan of providing early treatment with BT is more effective than the current approach. If we demonstrate that the treatment is effective we will be able to introduce this new method almost immediately within the NHS through our collaboration with doctors and therapists who are actively treating patients with this condition.

Ethics approval required
Old ethics approval format

Ethics approval(s)
North West 6 REC First MREC approval date 21/04/2011, ref: 10/H1003/111

Study design
Randomised interventional; Design type: Treatment

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Topic: Stroke Research Network; Subtopic: Rehabilitation; Disease: Drug type

Interventions
Patients will receive up to 200 Units of Botulinum Toxin (Botox) to 6 muscles of the upper limb.

Placebo group - Patients will receive 0.9% NaCl solution in to 6 muscles of the upper limb.

Follow Up Length: 6 month(s)

Intervention Type
Drug

Phase
Phase II

Drug/device/biological/vaccine name(s)
Botulinum toxin - type A

Primary outcome(s)
Action Research Arm Test; Timepoint(s): Baseline, 3 months and 6 months

Key secondary outcome(s))
1. In reducing focal spasticity in the arm as measured by surface electromyography (EMG) response of the wrist and elbow flexors to an externally imposed perturbation
2. In improving strength and fatigue as measured by maximum isometric strength and the rate of force production in the wrist and elbow joints
3. In reducing stiffness and increasing passive range of movement by measuring the range of movement and force required to produce the same with a custom built device
4. In preventing atrophy by measuring cross sectional thickness of biceps muscle as measured using 2D ultrasound - 12MHz probe
5. In reducing post stroke pain measured using a Scale of Pain Intensity (SPIN)
6. In improving quality of life (using the EuroQol Group EQ5D) and assessing carer giver burden (using the Care Giver Burden Scale)
7. In reducing the need for additional oral anti-spasmodic drugs or additional botulinum treatment during the course of rehabilitation
8. In reducing long term costs (quantified using resource utilisation diaries) and identifying discharge destination.
9. Occurrence of adverse events (AEs) during the study
10. In identifying changes in Therapeutic treatments as a consequence of injections

Completion date
31/12/2014

Eligibility

Key inclusion criteria
1. Over 18 years of age
2. Patients with stroke due to a primary cerebral haemorrhage/infarction, subarachnoid haemorrhage producing an upper motor syndrome affecting one body side which results in a hemiplegia
3. Capable of providing informed consent directly or indirectly, or, consent obtainable from next of kin or legal representative

4. No useful arm function (i.e. less than or equal to 2 on the grasp subsection of the Action Research Arm Test) at onset of spasticity.; Target Gender: Male & Female ; Lower Age Limit 18 years

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Significant musculoskeletal conditions that affected upper limb function prior to the stroke
2. Unconscious or moribund during the screening perid
3. Recovery of useful arm function (a score of 3 or more in the grasp section of the Action Research Arm Test) prior to injections
4. Patients with contraindications to electrical stimulation including active implants (e.g. cardiac assist devices), metal implants at site of stimulation, scar tissue/cancerous tissue at site of stimulation, uncontrolled epilepsy, deep vein thrombosis in limb / muscle being stimulated and pregnancy (or planned pregnancy)
5. Previousupper motor neurone syndrome or hypertonicity due to multiple sclerosis, spinal cord injury or other neurological disorder
6. Patients with a known hypersensitivity to any botulinum toxin or to any of the excipients of BOTOX® (i.e. Human serum albumin)
7. Patients with myasthenia gravis or Eaton Lambert Syndrome or other neuromuscular junction or myopathic disorder
8. Patients with infection at the proposed injection site(s)
9. Patients who are pregnant or may become pregnant at the time of the proposed injections and for the duration of the study
10. Current treatment with any antispasticity agent or previous injection with BOTOX

Date of first enrolment
03/10/2011

Date of final enrolment
31/12/2014

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Keele University
Newcastle
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ST5 5BG

Sponsor information

Organisation
Keele University (UK)

ROR
https://ror.org/00340yn33

Funder(s)

Funder type
Government

Funder Name
Research for Patient Benefit Programme

Alternative Name(s)
NIHR Research for Patient Benefit Programme, Research for Patient Benefit (RfPB), The NIHR Research for Patient Benefit (RfPB), RfPB

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	08/01/2014		Yes	No
Basic results				No	No
HRA research summary			28/06/2023	No	No