

# 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?

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<b>Registration date</b> 21/10/2011	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 12/06/2019	<b>Condition category</b> Circulatory System	<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

**EudraCT/CTIS number**  
2010-021257-39

**IRAS number**

**ClinicalTrials.gov number**  
NCT01882556

## Secondary identifying numbers

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

## Secondary study design

Randomised controlled trial

## Study setting(s)

Hospital

**Study type(s)**

Treatment

**Participant information sheet**

Not available in web format, please use the contact details to request a patient information sheet

**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 measure**

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

**Secondary outcome measures**

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

**Overall study start date**

03/10/2011

**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

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

Planned Sample Size: 150; UK Sample Size: 150

**Key exclusion criteria**

1. Significant musculoskeletal conditions that affected upper limb function prior to the stroke
2. Unconscious or moribund during the screening period
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. Previous upper 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**

England

United Kingdom

**Study participating centre**

**Keele University**

Newcastle

United Kingdom

ST5 5BG

## **Sponsor information**

**Organisation**

Keele University (UK)

**Sponsor details**

Keele

Newcastle

England

United Kingdom

ST5 5BG

**Sponsor type**

University/education

**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, RfPB

**Funding Body Type**

Government organisation

**Funding Body Subtype**

National government

**Location**

United Kingdom

## 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?
<a href="#">Basic results</a>				No	No
<a href="#">Protocol article</a>	protocol	08/01/2014		Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No