

The effect of botuline toxin A in the subscapular muscle in stroke patients with shoulder complaints; a randomized controlled trial.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27111

Source

NTR

Brief title

N/A

Sponsors and support

Primary sponsor: Allergan supplies the research medication

Intervention

Outcome measures

Primary outcome

1. Pain score (VAS);
2. Range of motion of glenohumeral joint.

Secondary outcome

N/A

Study description

Background summary

N/A

Study objective

We assume that relaxation of the subscapular muscle will lead to pain reduction and improvement of mobility in stroke patients with shoulder- or armpain and limited range of motion of the shoulder.

Study design

N/A

Intervention

Injection of 100 units of BOTOX (R) or 0.9% saline in subscapular muscle.

Contacts

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Eligibility criteria

Inclusion criteria

1. Stroke shoulder- or armpain longer than 1 week;
2. VAS pain 4 or higher;

Glenohumeral exorotation on the affected side is limited to 50% compared to the uninvolved side;

3. 18 years or older.

Exclusion criteria

1. Patients that cannot answer the painquestions;
2. Patients that cannot sit.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	01-11-2002
Enrollment:	50
Type:	Actual

Ethics review

Positive opinion

Date: 07-09-2005

Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL210
NTR-old	NTR247
Other	: p02.133
ISRCTN	ISRCTN28311224

Study results

Summary results

N/A