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The effect of botulinum toxin A in the subscapular muscle in stroke patients with shoulder complaints: a randomised controlled trial

Submission date
20/12/2005

Recruitment status
No longer recruiting

Registration date
20/12/2005

Overall study status
Completed

Last Edited
26/08/2021

Condition category
Musculoskeletal Diseases

[_] Prospectively registered
[_] 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)
Nil known

Protocol serial number
p02.133, NL210 (NTR247)

Study information

Scientific Title
The effect of botulinum toxin A in the subscapular muscle in stroke patients with shoulder complaints: a randomised controlled trial

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

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the local medical ethics committee

Study design
Randomised, placebo controlled, parallel group, triple blinded, multicentre trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Complaints of arm, complaints of shoulder

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

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Botulinum toxin A (BOTOX®)

Primary outcome(s)
1. Pain score (VAS)
2. Range of motion of glenohumeral joint

Key secondary outcome(s))
No secondary outcome measures

Completion date
01/11/2006

Eligibility

Key inclusion criteria
1. Stroke shoulder- or arm pain longer than one week
2. Visual Analogue Scale (VAS) pain four or higher
3. Glenohumeral exorotation on the affected side is limited to 50% compared to the uninvolved side
4. 18 years or older

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Not Specified

Lower age limit
18 years

Sex
Not Specified

Total final enrolment
21

Key exclusion criteria
1. Patients that cannot answer the pain questions
2. Patients that cannot sit

Date of first enrolment
01/11/2002

Date of final enrolment
01/11/2006

Locations

Countries of recruitment
Netherlands

Study participating centre
Medical Centre Haaglanden
Den Haag
Netherlands
2501 CK

Sponsor information

Organisation
Medical Centre Haaglanden (The Netherlands)

ROR
https://ror.org/00v2tx290

Funder(s)

Funder type
Industry

Funder Name
Allergan (The Netherlands)

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		11/04/2008	26/08/2021	Yes	No