

Use of botulinum toxin-A for musculoskeletal pain in patients with whiplash associated disorders

Submission date 01/02/2004	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 02/02/2004	Overall study status Completed	<input checked="" type="checkbox"/> Protocol
Last Edited 24/08/2007	Condition category Injury, Occupational Diseases, Poisoning	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Study information

Scientific Title

Acronym
Whibotulin

Study objectives

Not provided at time of registration

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Whiplash cervical injuries

Interventions

Randomised, prospective, double blind, placebo-controlled study comparing Botox® with placebo.

The study evaluates the efficacy and safety of Botox® in patients with musculoskeletal pain after whiplash associated disorders.

1. Subjective pain
2. Assessment of disability due neck pain with the Neck Pain Disability Index
3. Assessment of Range Of neck Motion (ROM), using CROM® Cervical Range of Motion Instrument
4. Assessment of health status

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Botulinum toxin-A

Primary outcome(s)

Not provided at time of registration

Key secondary outcome(s)

Not provided at time of registration

Completion date

01/01/2005

Eligibility

Key inclusion criteria

1. Patients with grade II Whiplash Associated Disorders (WAD) of Quebec Task Force (QTF)-WAD
2. Neck pain secondary to cervical whiplash injury with musculoskeletal signs of greater than three months
3. Aged greater than 18 years
4. Lack of response to conventional physical and medical therapy

Musculoskeletal signs:

1. Palpable band, spot tenderness, and jump sign in cervical muscles or restricted range of motion in cervical spine
2. Demonstrated precipitation of neck pain with external pressure over the occipital or cervical region on affected side
3. Myofascial pain of cervical muscles
4. Experienced pain on maneuver of stretching
5. Trigger point with associated referred pain

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

Not Specified

Key exclusion criteria

1. Serious somatic or psychiatric illness
2. Anticoagulation therapy
3. Myasthenia gravis
4. Pregnancy or breast-feeding
5. Abnormal anatomy
6. Rheumatoid disease or radiculopathy
7. Need for regular analgesic for severe pain

Date of first enrolment

01/01/2004

Date of final enrolment

01/01/2005

Locations

Countries of recruitment

Spain

Study participating centre

Salamanca, 5

Vigo

Spain

36211

Sponsor information

Organisation

Povisa Medical Center (Povisa Centro Medico) (Spain)

ROR

<https://ror.org/043m85342>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Povisa Medical Center (Spain)

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?
Protocol article	Protocol	13/02/2004		Yes	No