

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

<b>Submission date</b> 01/02/2004	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 02/02/2004	<b>Overall study status</b> Completed	<input checked="" type="checkbox"/> Protocol
<b>Last Edited</b> 24/08/2007	<b>Condition category</b> 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

### Contact name

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

# 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

## Secondary study design

Randomised controlled trial

## Study setting(s)

Not specified

## Study type(s)

Treatment

## Participant information sheet

## 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 measure**

Not provided at time of registration

**Secondary outcome measures**

Not provided at time of registration

**Overall study start date**

01/01/2004

**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

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Not Specified

**Target number of participants**

160

**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)

**Sponsor details**

Salamanca, 5

Vigo

Spain

36211

**Sponsor type**

Hospital/treatment centre

**ROR**

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

# Funder(s)

## Funder type

Hospital/treatment centre

## Funder Name

Povisa Medical Center (Spain)

# 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="#">Protocol article</a>	Protocol	13/02/2004		Yes	No