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

Submission date	Recruitment status	[ ] Prospectively registered
01/02/2004	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
02/02/2004	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
24/08/2007	Injury, Occupational Diseases, Poisoning	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Francisco J Juan

Contact details
Salamanca, 5
Vigo
Spain
36211
+34 986 413 144
j.juan@arrakis.es

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?
Protocol article	Protocol	13/02/2004		Yes	No