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Retrospective study on the evaluation of chronic and long-term pain therapeutics to manage post-traumatic cervical dystonia

Submission date
27/03/2017

Recruitment status
No longer recruiting

Registration date
07/04/2017

Overall study status
Completed

Last Edited
06/04/2017

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Neck pain is a very common condition, which can be cause great discomfort and restriction of movement. Whiplash injury is a common type of neck injury caused by sudden movement of the head forwards, backwards or sideways. It occurs when the soft tissues in the neck become stretched and damaged, often due to wearing a seatbelt in a roach traffic accident. Pain from whiplash often lasts for months and for some can severely limit their activities. Treatment often involves taking painkillers in combination with physiotherapy. Studies have shown that botox injections can help to relief long-term pain. It works by blocking nerve pathways that are causing pain and allowing nerve pathways to form without pain. The aim of this study is to review the medical records of people who have had botox treatment for neck pain as part of their usual care to look at its effectiveness.

Who can participate?
Adult patients who have long-term neck pain after whiplash from a road traffic accident.

What does the study involve?
Patients who have neck pain after a road traffic accident for whom taking pain killers have not worked for six weeks receive a botox injection into their neck muscles as part of their normal care. These patients then return to follow up appointments where their pain levels and ability to move their necks is assessed using a questionnaire and a physical examination after six weeks and 90 days. This study involves this information being collected from medical records in order to see how effective the treatment has been.

What are the possible benefits and risks of participating?
There are no direct benefits or risks involved with participating in this study.

Where is the study run from?
Advanced Pain Specialists, PLLC. (USA)

When is the study starting and how long is it expected to run for?
October 2015 to March 2017

Who is funding the study?
Investigator initiated and funded (USA)

Who is the main contact?
Dr Ricardo Borrego

Contact information

Type(s)
Public

Contact name
Dr Ricardo Borrego

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48124

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Retrospective Study 1

Study information

Scientific Title
Effect of Botulinum toxin with physical therapy on patients with post-traumatic cervical dystonia is effective to manage long-term, chronic pain

Study objectives
Primary study aim:
The aim of this study is to evaluate the efficacy of opioids and NSAIDs to relieve acute pain while treating long-term pain with botulinum toxin.

Secondary study aim:
The aim of this study is to explore the pain relieving capabilities of botulinum toxin in patients with post-traumatic cervical dystonia.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethical approval is not required for the following reasons:
1. The paper does not report on the use of experimental or new protocols. The treatment protocol evaluated is the national protocol and is performed in accordance with the indication for botulinum toxin
2. This is not a program set up as a study or research project. These patients willingly sought treatment.
3. The analysis looked retrospectively at outcomes for a small cohort of patients treated. This was done internally and as part of the standard of care that patients sought in the researcher's clinic.

Study design
Retrospective chart review

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
GP practice

Study type(s)
Other

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Post-traumatic cervical dystonia

Interventions
All participants have been diagnosed with cervical dystonia caused after trauma from a motor vehicle accident. They receive care as usual in the emergency room and from a primary care physician, who prescribes the patient with narcotic or non-narcotic analgesics and physical therapy (normal care). Patients who do not respond to therapy from 6 weeks of normal care are then referred to Advanced Pain Specialists, PLLC., from whom they receive botulinum toxin (Botox, Botulinum Toxin Type-A, Allergan, Irvine, California) injections at a dose depending on the size of muscle group in the neck (intervention as part of normal care).

This study involves the review of these patient's medical charts. VAS scores for pain and range of motion from physical examinations at the initial visit (baseline, six weeks and 90 days is collected and reviewed by the investigator.

Intervention Type
Mixed

Primary outcome measure
Pain, as measured using the visual analogue scale at baseline, within 6 weeks and within 90 days weeks of receiving botulinum toxin and assessed through medical record review.

Secondary outcome measures
Range of motion, as measured by physical examination at baseline, within 6 weeks and within 90 days weeks of receiving botulinum toxin and assessed through medical record review.

Overall study start date
05/10/2015

Completion date
01/03/2017

Eligibility

Key inclusion criteria
1. Soft tissue injury resulting in cervical dystonia neck distortion following a motor vehicle accident
2. Range of motion limited to laterocollis and shoulder elevation
3. Experienced neck pain after trauma and were prescribed physical therapy either opioids or NSAIDs
4. Pain symptoms lasting 14 – 16 weeks from initial trauma
5. Patients attended 3 physical therapy sessions per week
6. Toronto Western Spasmodic Torticollis Rating Scale (TWISTRS) greater than 35
7. Visual analogue scale (VAS) score greater than 7
8. Presence of hernia on magnetic resonance imaging (MRI)
9. Aged 18 years and over

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
20

Key exclusion criteria

1. Patients solely on muscle relaxer medication to relieve pain
2. Less than 18 years of age
3. Pregnancy or breast feeding
4. Diagnosed neuromuscular disorders
5. Previous use of botulinum toxin

Date of first enrolment
25/01/2016

Date of final enrolment
25/02/2016

Locations

Countries of recruitment
United States of America

Study participating centre
Advanced Pain Specialists, PLLC.
18100 Oakwood Blvd
Suite 203.
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48124

Sponsor information

Organisation
Advanced Pain Specialists, PLLC

Sponsor details
18100 Oakwood Blvd
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Sponsor type
Industry

Funder(s)

Funder type

Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Planned publication in a peer reviewed, open access journal.

Intention to publish date
31/12/2017

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Ricardo Borrego, MD, MSBA.; Advanced Pain Specialists, PLLC (rdborrego@aol.com)

IPD sharing plan summary
Available on request