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An investigation on spinal fluid in patients with sciatica-type or nerve-type pain of the lower limb

Submission date
27/05/2019

Recruitment status
No longer recruiting

Registration date
04/07/2019

Overall study status
Completed

Last Edited
17/11/2023

Condition category
Nervous System 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
PD-1 and PD-L1 are proteins found on the surface of cells that are involved in immune responses (defence against foreign substances) in the human body. We currently know, the cause of neuropathic pain is associated with an unusual immune response. Identification of these proteins in patients with neuropathic pain may suggest a potential target for the treatment of neuropathic pain in the future.
We aim to investigate the presence of PD-1 and PD-L1 in the spinal fluid of patients with neuropathic pain.

Who can participate?
Patients with chronic radicular pain who are scheduled to undergo pulsed radiofrequency treatment (PRF).

What does the study involve?
The study involves performing a lumbar puncture on patients with neuropathic pain, to sample cerebrospinal fluid (CSF) and perform flow cytometry analysis on these samples to identify if PD-1 and PD-L1 are present and on which cells.

What are the possible benefits and risks of participating?
Possible benefits include the identification of a new target for the treatment of neuropathic pain. All patients will have standard treatment given as currently recommended (PRF to DRG) and will be offered subsequent repeat procedure if a benefit is seen.
Potential risks include the 1 in 200 risk of developing a post dural puncture headache secondary to the lumbar puncture. The risk of this is reduced as much as possible by the use of the smallest lumbar puncture needle with needle least likely to cause tearing of spinal fibres.

Where is the study run from?
St James Hospital, Dublin.

When is the study starting and how long is it expected to run for?
October 2018 to July 2023

Who is funding the study?
Investigator funded

Who is the main contact?
Dr Deborah Galvin,
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Contact information

Type(s)
Public

Contact name
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
2016-12 List 47 97, 2018-10 List 33

Study information

Scientific Title
An investigation on cerebrospinal fluid (CSF) concentrations of PD-1 and PD-L1 and quantification of cellularity of CSF in patients with chronic radicular lumbar pain

Acronym
PD 1 Study

Study objectives
To investigate the presence of PD-1 and PD-L1 in patients with chronic radicular lumbar pain

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 18/10/2019, SJH/TUH Research Ethics Committee (Tallaght University Hospital, Tallaght, Dublin 24, D24 NR0A; ResearchEthics@tuh.ie; +353(0)1-414 2199), ref: 2016-12 List 47 97, 2018-10 List 33 (10) (8).

Study design
Cross-sectional observational trial

Primary study design
Observational

Secondary study design
Case series

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Neuropathic lower limb pain

Interventions
Patients are undergoing pulsed radiofrequency treatment (PRF). CSF is taken at the time of the procedure (just before it is performed) via lumbar puncture with subsequent flow cytometry performed. It is performed by the principal investigator.
(PRF consists of 120 seconds of electric current to the dorsal root ganglion (nerve root) of the spinal nerves in the back which results in a change in the activity or "firing" of the nerve. Routine follow-up is at 3 months post-procedure or sooner at patient request.)

Follow-up data consists of all patients being routinely reviewed at an outpatient appointment 3 months later (consisting of direct questioning and a repeat completion of a neuropathic pain questionnaire called DN4- already completed by them prior to first CSF sampling). Contact details for the pain department are given to all participants after the procedure regarding any issues after the procedures.

Intervention Type

Procedure/Surgery

Primary outcome measure
Presence of PD-1 and PD-L1 in the patients spinal fluid (as quantified by flow cytometry)

Secondary outcome measures
Change in pain score of patient at 3 month interview and use of Douleur Neuropathique pain questionnaire at baseline (day of procedure) and 3 months later (when back in clinic)

Overall study start date
03/09/2018

Completion date
31/07/2023

Eligibility

Key inclusion criteria
1. Chronic radicular pain
2. Scheduled to undergo pulsed radiofrequency treatment (PRF).

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
12

Key exclusion criteria
Coagulopathy

Date of first enrolment
24/10/2018

Date of final enrolment
31/03/2023

Locations

Countries of recruitment
Ireland

Study participating centre

St James Hospital
Dept. of Pain
James Street
Dublin
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Sponsor information

Organisation
Trinity Translational Medicine Institute

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Sponsor type
University/education

Website
https://www.tcd.ie/ttmi

ROR
https://ror.org/02tyrky19

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan

Aiming for International Pain Journal or Immunology Journal

Intention to publish date
30/06/2024

Individual participant data (IPD) sharing plan
All data generated or analysed during this study will be included in the subsequent results publication

IPD sharing plan summary
Other