

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	<input type="checkbox"/> Prospectively registered
Registration date 04/07/2019	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 17/11/2023	Condition category Nervous System Diseases	<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

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

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
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

Study type(s)

Diagnostic

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(s)

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

Key secondary outcome(s)

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)

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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

Ireland

D8

Sponsor information

Organisation

Trinity Translational Medicine Institute

ROR

<https://ror.org/02tyrky19>

Funder(s)

Funder type

Other

Funder Name

Investigator initiated and funded

Results and Publications

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