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A study to evaluate the effect of the time interval between spinal tap procedure on the chemistry measurements in blood and in the fluid surrounding the brain and spinal cord in healthy participants

Submission date 12/09/2023	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 15/09/2023	**Overall study status** Completed	
Last Edited 04/12/2023	**Condition category** Other	

Plain English summary of protocol

Background and study aims
This study is testing the effects of a common procedure during which a needle is inserted into the lower spine known as lumbar puncture (also called a spinal tap) on chemistry measurements in blood and in the fluid surrounding the brain and spinal cord (known as cerebrospinal fluid [CSF]). Chemistry measurements in blood and CSF are often used to monitor the development of disorders that affect the brain and nerves found throughout the human body and spinal cord (neurological disorders). These measurements also help to find out how the brain and body respond to treatment. The purpose of this study is to test repeated lumbar punctures performed at different time intervals (3 days, 7 days, 14 days, or 28 days apart) to find out the effect of different time intervals on chemistry measurements in the blood and CSF. The study also aims to find out how the different time intervals affect the safety and tolerability of the procedure.

Who can participate?
Healthy people aged between 18 to 50 years old

What does the study involve?
Participants will be part of this study for approximately 2 months. The study will be conducted in the following parts:

1. Screening - During the screening period, participants will undergo certain screening tests and /or procedures to make sure that they are eligible to take part in this study. Participants will have one clinic visit and the screening period will be for approximately 28 days.

2. Procedure period - During this period, participants will be assigned to one of the four groups to undergo two lumbar punctures. Participants will be required to visit the clinic on the day of

the lumbar puncture and will be discharged from the clinic later that day after a post-procedure observation period. Participants will undergo their first lumbar puncture on Day 1 and will undergo the 2nd one either on Day 4, 8, 15, or 29 depending on the group they are assigned to. Participants will have to report to the clinic 2 times for lumbar puncture, routine check-ups, and blood tests.

3. Follow-up - One day after the 1st and 2nd lumbar puncture, participants will be contacted by phone call to check on their wellbeing and ask about any side effects from the study procedures.

What are the possible benefits and risks of participating?
It is not intended that participants will receive any benefit from this study, but the information learned from this study may help people with neurological disorders in the future.

Participants may have side effects from the study procedures used in this study. Side effects can vary from mild to very serious and may be different from person to person.

Risks Associated with Study Procedures
1. Lumbar puncture: It involves the removal of CSF (about 1 tablespoon) that surrounds your brain and spinal cord by inserting a needle between two lumbar bones (vertebrae) in the lower back. Participants will undergo two lumbar punctures, separated by one of the intervals (3, 7, 14, or 28 days).

The risks and discomforts associated with the lumbar puncture may include pain, feeling sick (nausea), headache, discomfort, bruising, stiffness, and, rarely, infection. Occasionally, during needle insertion, a spinal nerve is touched, causing pain to spread to the buttock or leg. This usually lasts only a short time. Rarely, participants may experience vomiting, bleeding into the spinal canal, or spinal canal nerve damage. Participants may have an allergic reaction to the medication used to numb the area (local anesthetic) where the needle is inserted.

Participants who are pregnant, currently breastfeeding, or planning to become pregnant during the study cannot take part in the study.

Where is the study run from?
Genentech Inc (Switzerland)

When is the study starting and how long is it expected to run for?
June 2023 to July 2024

Who is funding the study?
Genentech Inc (USA)

Who is the main contact?
global.trial_information@roche.com

Contact information

Type(s)
Public

Contact name
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Additional identifiers

Protocol serial number
GN44993

Study information

Scientific Title
Evaluation of the effects of interval between lumbar punctures on cerebrospinal fluid and blood analytes in healthy volunteers

Study objectives
The main purpose of this study is to determine the effect of inter-lumbar puncture (LP) interval duration on cerebrospinal fluid (CSF) biomarkers.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 04/09/2023, Northern B Health and Disability Ethics Committees, Ministry of Health (133 Molesworth Street, Wellington, 6011, New Zealand; +64 0800 400 569; hdec@health.govt.nz), ref: 2023 EXP 18067

Primary study design
Observational

Study design
Single center non-randomized observational cohort study

Study type(s)
Other

Health condition(s) or problem(s) studied
Healthy Volunteers

Interventions
Cohort A: Participants will undergo a lumbar puncture procedure on Day 1 and another one 3 days later on Day 4.

Cohort B: Participants will undergo a lumbar puncture procedure on Day 1 and another one 7 days later on Day 8.

Cohort C: Participants will undergo a lumbar puncture procedure on Day 1 and another one 14 days later on Day 15.

Cohort D: Participants will undergo a lumbar puncture procedure on Day 1 and another one 28 days later on Day 29.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Validity, stability, and variability of CSF analyte values across different inter-LP interval durations measured using the relative and absolute inter-LP differences for CSF analyte values in each cohort using CSF fluid collected during LP on Days 1, 4, 8, 15, and 29

Key secondary outcome(s)
1. Number of participants with adverse events (AEs), and severity of AEs measured according to Division of AIDS (DAIDS) toxicity scale from screening (Day -28) up to follow-up (Up to Day 30)
2. Stability and variability of plasma and serum analyte values across different inter-LP interval durations measured using the relative and absolute inter-LP differences for plasma or serum analyte values in each cohort using blood samples collected during LP on Days 1, 4, 8, 15 and 29

Completion date
31/07/2024

Eligibility

Key inclusion criteria
1. Participants must have a total body weight between 45 and 120 kilograms (kg), inclusive
2. Good health, demonstrated by no clinically significant findings from medical history, physical examination, laboratory tests, and vital signs
3. Agreement not to have any additional blood draws or CSF sampling for the duration of the study
4. No contraindication to lumbar dural puncture, including coagulopathy, concomitant anticoagulation, thrombocytopenia, prior lumbar spinal surgery, abnormal brain imaging, or other factor that precludes safe LP in the opinion of the investigator

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit
50 Years

Sex
All

Key exclusion criteria
1. Treatment with any vaccine within 14 days prior to Day 1 or vaccination scheduled to occur during the study
2. Poor peripheral venous access
3. History of seizures, with the exception of childhood febrile seizures
4. History of prior traumatic brain injury graded as moderate or severe
5. Abnormal brain imaging findings that preclude safe LP
6. History of schizophrenia, schizoaffective disorder, or bipolar disorder
7. History of malignancy
8. Positivity for tuberculosis (TB) during screening or within 3 months prior to screening
9. Positive human immunodeficiency virus (HIV) test at screening
10. Positive hepatitis B surface antigen (HBsAg) test at screening
11. Positive hepatitis C virus (HCV) antibody test at screening

Date of first enrolment
16/10/2023

Date of final enrolment
04/03/2024

Locations

Countries of recruitment
New Zealand

Study participating centre
New Zealand Clinical Research
New Zealand
8011

Sponsor information

Organisation
Genentech

ROR
https://ror.org/04gndp242

Funder(s)

Funder type
Industry

Funder Name
Genentech

Alternative Name(s)
Genentech, Inc., Genentech USA, Inc., Genentech USA

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analyzed during the current study are not expected to be made available due to participant-level data not being a regulatory requirement.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Study website	Study website	11/11/2025	11/11/2025	No	Yes