ForPatients
by Roche

Healthy Volunteers

A study to find out how time between two lumbar punctures affects samples collected from the second lumbar puncture

Evaluation of the Effects of Interval Between Lumbar Punctures on Cerebrospinal Fluid and Blood Analytes in Healthy Volunteers

Trial Status	Trial Runs In	Trial Identifier
Completed	1 Country	ISRCTN13868766 GN44993

The information is taken directly from public registry websites such as ClinicalTrials.gov, EuClinicalTrials.eu, ISRCTN.com, etc., and has not been edited.

Official Title:

A single site, non-randomized, open-label study to investigate the impact on fluid biomarkers and safety of multiple lumbar punctures in healthy volunteers.

Trial Summary:

This study was done to understand how the timing between two lumbar punctures affects samples. Researchers wanted to find out how soon a second sample could be taken and still be similar to the first sample. Healthy volunteers (people without health problems) joined one of four groups. They gave two samples of the fluid that surrounds the brain, collected through lumbar puncture (spinal tap). The first sample was taken on Day 1. The second was taken on a different day for each group. Then, the samples were analyzed and compared to each other within each group. There were some risks for participants, such as feeling sore from the lumbar puncture, or having headaches or nausea. However, the researchers took many steps to keep everyone safe and believed the procedure was safe for the people in this study. The information learned from this study would help in designing large studies to test new medicines for brain diseases such as Alzheimer's.

Genentech, Inc. (A part of F. Hoffmann-La Roche Ltd., Switzerland)	Phase 1
Sponsor	Phase

ISRCTN13868766 GN44993
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers

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Both	18 to 50 years (inclusive)	Yes

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 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 safety and tolerability of the procedure.

Who can participate?

Healthy people between 18 to 50 years of age can participate in this study.

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 would 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

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 spinal canal, or spinal canal nerve damage. Participant 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.

Who is funding the study?

Genentech Inc (United States)

Who is the main contact?

global-roche-genentech-trials@gene.com

Inclusion Criteria:

- Participants must have a total body weight between 45 and 120 kilograms (kg), inclusive
- Good health, demonstrated by no clinically significant findings from medical history, physical examination, laboratory tests, and vital signs
- Agreement not to have any additional blood draws or CSF sampling for the duration of the study

- 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

Exclusion Criteria:

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