ForPatients
by Roche

Healthy Volunteers

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
Recruiting	1 Countries	GN44993

The source of the below information is the publicly available website ClinicalTrials.gov. It has been summarised and edited into simpler language.

Trial Summary:

A Study to Evaluate the Effect of Time Interval Between Spinal Tap Procedure on the Chemistry Measurements in Blood and in Fluid Surrounding the Brain and Spinal Cord in Healthy Participants

Genentech Inc (United States)
Sponsor

GN44993
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
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?

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