ForPatients
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Healthy Volunteers

A study to investigate the processing by the body, safety, and side effects of gantenerumab in healthy Chinese participants following a single dose

A single-center, open-label, Phase I study to investigate the pharmacokinetics, safety, and tolerability of gantenerumab in healthy Chinese participants following single subcutaneous administration of a high-concentration liquid formulation in the abdomen

Trial Status	Trial Runs In	Trial Identifier
Active, not recruiting	1 Countries	YP40254

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

Trial Summary:

Alzheimer's disease (AD) is the most common form of dementia, accounting for 60%-70% of cases. The prevalence of AD increases with age, with a global prevalence of 5%- 8% in people 60 years and older. Because of its increasing prevalence, long duration, and high cost of care, AD is expected to be a major public health problem for decades to come. AD is thought to be caused by an abnormal build-up of proteins in the brain resulting in a loss of brain cells. Treatments targeting the processing and deposition of protein may alter the progression of AD. Gantenerumab (RO4909832) is an antibody that binds specifically to amyloid-beta (a brain protein fragment and prime suspect in AD), promoting its clearance. This single-dose study in healthy participants has been designed to support the development of gantenerumab for the treatment of patients with AD in China.

YP40254
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
Male and Female	18 to 60 years	yes

Who can participate?
Healthy Chinese male and female volunteers

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What does the study involve?
On day one, participants will receive a single dose of gantenerumab as two injections, one in the lower quadrant and one in the upper quadrant of the abdomen. Blood levels of gantenerumab are measured at pre-dose, Day 1, 2, 3, 4, 5, 6, 7, 8, 12, 21, 29, 43, 64 and 85.

What are the possible benefits and risks of participating?
Gantenerumab has been well-tolerated in patients with AD. The dosage is within the range of recently conducted clinical trials in healthy participants; all tested doses were considered safe and well-tolerated. There are two identified risks for the compound: amyloid-related imaging abnormalities (ARIA) are abnormal differences seen in brain imaging of AD patients, observed following repeated treatment in patients with AD, and integrated stress response (ISR). In previous single-dose studies of gantenerumab, in participants with AD, ARIA has not been observed. As with any medicinal product, the potential for a hypersensitivity reaction with gantenerumab cannot be excluded. Therefore, the participants will be closely monitored during injection and for 24 hours after treatment, and medications for the treatment of hypersensitivity reactions will be available. Overall, based on previous studies with gantenerumab and the careful monitoring of safety parameters within this study, the risks for the participants in this study are considered acceptable.
No therapeutic benefit is anticipated for the participants participating in this study. The results from this study may guide the future development of gantenerumab for the treatment of patients with AD.

Where is the study run from?
Huashan Hospital Affiliated to Fudan University (China)

When is the study starting and how long is it expected to run for?
June 2020 to October 2021

Who is funding the study?
Genentech, Inc. (USA)

Who is the main contact?
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