

Scott & White Hospital & Clinics Clinical Research at Scott & White

Please complete this form for each of your studies that are currently enrolling subjects. This information will be used to create a web page available for viewing by the general public. Please use lay terminology as in the consent form. The information should be complete and accurately describe your studies.

Study Title: A Phase 3, Multi-Center, Randomized, Double-Blind, Controlled Study of the Long-Term Analgesic Efficacy and Safety of Tanezumab Alone or in Combination with Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) Versus NSAIDs Alone in Patients with Osteoarthritis of the Knee or Hip (Protocol #: A4091025)

Project ID#: 81651

Department: Rheumatology

Sponsor: Pfizer, Inc.

1. Provide a brief synopsis of the study (purpose of the study from abstract, consent form, or protocol using lay terminology):

Condition(s):	Treatment(s):
You have been diagnosed with osteoarthritis of the knee or hip.	<ul style="list-style-type: none"> • Tanezumab (5 or 10 mg) IV • NSAID therapy (naproxen 500 mg tablet or celecoxib 100 mg capsule) • matching Tanezumab and NSAID placebo (control)

Arthritis is a condition involving damage to the bone joint. The most common form of arthritis is Osteoarthritis (OA). OA is a progressive (worsening) disease that commonly affects the larger weight-bearing joints in the body such as the knees and hips.

The purpose of this research study is to determine whether an investigational drug, called tanezumab, can effectively and safely relieve the symptoms of OA when used alone or in combination with an NSAID (non-steroidal anti-inflammatory drug). Tanezumab has not been approved for use by the U.S. Food and Drug Administration (FDA) and is considered experimental.

2. Who is eligible to participate in the study (basic qualifications such as age, gender, etc.)?

Age: 18 years or older

Gender: Men and Women

- You must have a current diagnosis of OA of the knee or hip.

Patients **cannot** participate in this study if the following apply:

- You are currently pregnant or breastfeeding
- You have a history of any disease that may involve the knee or hip.

- You have a history of any significant disease (i.e., heart, nervous system, mental)
- You have a known or suspected cancer.
- You have participated in another clinical trial within the last 4 weeks.
- You are not able or are unwilling to comply with all of the study requirements for the duration of the study.

**** In order to be eligible to participate, you must meet other entry criteria as required by the study protocol and indicated by the study doctor.**

3. What may be involved/required for subject participation (visits, tests, and/or logs, etc.)?

If you agree to take part in this study, your participation will last up to 60 weeks (14 months), during which time you will be required to visit the clinic at least 12 times. Each clinic visit will last 1-3 hours.

Participation in this study will involve a screening period to determine your eligibility. If you qualify, you will be randomly assigned (like the flip of a coin) to one of 5 treatment groups for a period of 56 weeks:

- tanezumab 5 mg plus NSAID
- tanezumab 10 mg plus NSAID
- tanezumab 5 mg plus NSAID placebo
- tanezumab 10 mg plus NSAID placebo
- tanezumab placebo plus NSAID

Placebo is an inactive substance that looks like the study drug (tanezumab or NSAID) except that it provides no medical benefit. You will not know which treatment group you have been assigned to until your participation in the study is complete.

The following tests and procedures will be performed during the course of this research study:

- Physical examination including height, weight, and vital signs.
 - Medical history including medications.
 - X-ray performed on your knee or hip.
 - Neurological examination - a test that measures your level of awareness, strength, coordination, and balance.
 - Electrocardiogram (ECG) - a test that measures the electrical activity of your heart.
 - Routine blood/urine tests.
 - Serum/urine pregnancy tests.
 - Completion of four questionnaires - used to evaluate your symptoms of OA and how they affect your ability to perform daily activities.
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4. Contact Information:

Coordinator(s): Carla Brown

Title(s): Clinical Research Coordinator

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