



VASCULITIS
CLINICAL
RESEARCH
CONSORTIUM

Clinical Trial of
Abatacept for

Giant Cell Arteritis & Takayasu's Arteritis

What is this study?

Our protocol has been funded by the National Institutes of Health and each VCRC site is currently undergoing local safety board review. This study is not yet open for participation.

Giant cell arteritis (GCA) and Takayasu's arteritis (TAK) are diseases that cause inflammation of the large arteries of the head, neck, upper body, abdomen, arms, and legs. Therapies are available to improve the symptoms of GCA and TAK, but relapse often occurs such that better treatments are needed. In this study, we are seeking to evaluate the effectiveness and safety of the medication abatacept in GCA and TAK. In this study, all people will initially receive abatacept and prednisone. After 3 months, if a person is in remission, they will either continue abatacept or be switched to a placebo (a sterile salt solution). This treatment assignment is determined by a computer using a process called randomization.

What does this study involve?

This is a treatment study that occurs at several hospitals, and will seek to randomize a total of 66 people, 33 with GCA, and 33 with TAK. In this study abatacept is given intravenously at study visits on Days 1, 15, 29 and at Month 2. Randomization takes place at Month 3. Participation in this study may last between 12 and 48 months. Study visits include the following:

- abatacept infusions
- blood tests; for clinical and for research purposes
- questionnaires to measure quality of life
- chest x-rays and CT scans of the chest and/or sinuses

Who qualifies?

To participate, you must:

1. have a diagnosis of GCA or TAK
2. have presence of active GCA or TAK within the past 2 months
3. be 18 years of age or older
4. be willing and able to follow treatment and follow-up procedures
5. be willing to use an effective means of birth control during this study
6. be willing and able to give written informed consent

Why participate?

By participating in this clinical trial you will help researchers better understand Giant Cell Arteritis and Takayasu's Arteritis and work toward developing more effective and safer therapies.

Where will the study take place?

How do I participate?

If you are interested in participating in this study or would like additional information, please contact a study coordinator at the clinical center most convenient for you:

Boston University School of Medicine, Boston, Massachusetts

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