Northwest Rheumatology Associates, P.C.
9555 SW Barnes Road - Suite 150 – Portland, Oregon 97225
Telephone: (503) 297-3384 - Fax: (503) 297-0863
www.nwrheumatology.org

INFORMED CONSENT FOR TREATMENT WITH ANAKINRA or CANAKINUMAB

Anakinra has been approved by the Food and Drug Administration (FDA) for the treatment of Rheumatoid Arthritis. Canakinumab has been FDA approved for treatment of Still's disease and Periodic fever syndromes.

These drugs block the action of a protein called Interleukin-1 (IL-1). This blockade may result in decreased swelling (inflammation) and decreased immune system function (immunosuppression).

ADVERSE EFECTS

Injection site reactions – are rhe most common side effect are such as redness, swelling, bruising, itching or hives. It typically will occur in the first month of treatment and usually resolves within one month.

Allergic reactions – tell your provider if you experience any of the following after an injection – difficulty breathing or swallowing, wheezing, rash, itching, hives, nausea, dizziness, fainting, low blood pressure or palpitations.

These drugs decrease immune system function (immunosuppression), which can result in serious infections or worsening of an existing infection. Death from serious infections can occur.

Tell your doctor if you have any symptoms of an infection e.g pink eye, ear pain or drainage, sinus pain or drainage, sore throat, hoarse voice, cough, difficulty breathing, fevers, chills, sweats, vomiting, abdominal pain, diarrhea, burning with urination, increased frequency of urination, vaginal discharge, and cuts or wounds that are red, swollen or draining pus.

Tell your doctor if you have been diagnosed with an infection, are on antibiotics or if you are prone to recurrent infections. You should not receive these medicines while you have an active infection or while you are on antibiotics. These medicines can be restarted once you have completed your antibiotic course and your infection has resolved.

Anakinra and canakinumab can drop your blood counts, particularly in your white blood cell count which is important in fighting infection. Your blood cell counts will be monitored while you are on treatment.

Patients with prolonged inflammation and chronic immunosuppression are more prone to develop cancer, in particular lymphoma. The impact of anakinra or canakinumab on this is not known.

Other side effects not listed above can also occur in some patients. Tell your doctor if you develop any problems.

PRECAUTIONS

Tell your doctor if you have a planned surgery, as you will need to stop your medicine temporarily around the time of your surgery.
It is not known if anakinra or canakinumab can cause fetal harm when given during pregnancy, or safety while breast feeding. You should consult the pros and cons of continuing treatment with these medications with your rheumatologist and your obstetrician before planning conception.
You should not take these drugs with other biologic medications such as remicade, humira, actemra, orencia etc.
You should not receive live vaccines (for eg. Polio, smallpox, Zostavax, live flu vaccines) while on these medications. Killed vaccines such as injected flu vaccine, pneumonia, shingrix vaccines can be safely administered.

MEDICATION ADMINISTRATION:

Anakinra is injected under the skin every day. Canakinumab is injected under the skin once a month. You will be taught how to do the injections.

EMERGENCY CONTACTS:

In case of emergency, you can contact our office at (503) 297-3384 from 8:00 am to 5:00 pm Monday – Friday, or after hours dial the above number to page your physician or call 911 or go to the emergency room.

I certify that I have read and understand this consent form and agree to receive and self administer anakinra. I have had an opportunity to discuss this treatment with my physician and ask questions regarding the treatment. I will be given a signed copy of this form for my records.

_____ _____

Patient signature Date