

Adacolumn[®] Research Studies

for ulcerative colitis and Crohn's disease



What is being tested?

The **Adacolumn Apheresis System**, an investigational medical device, is being tested to evaluate its safety and effectiveness as a potential treatment for ulcerative colitis and Crohn's disease. The Adacolumn Apheresis System is a process that selectively removes from the blood specific white blood cells called monocytes and granulocytes that have been shown to be associated with inflammation, tissue damage, and disease symptoms in patients with ulcerative colitis and Crohn's disease.

How does Adacolumn work?

Blood is withdrawn from the participant's arm through a tube and pumped through a column filled with beads made of cellulose acetate. As the blood flows through the column, monocytes and granulocytes are removed by the beads and the blood then returns to the participant's body through the other arm. The procedure takes about 60 minutes. The most common side effects (serious and non-serious) include headache, nausea, fatigue, urinary tract infection, swelling from a broken vessel at the blood draw site and bruising. Serious uncommon side effects (observed in 1% of patients) include stroke and blood clot in the lungs.

Why are these medical research studies being conducted?

The goal of these clinical studies is to evaluate whether the Adacolumn Apheresis System can safely and effectively reduce the symptoms associated with ulcerative colitis and Crohn's disease.

Who is eligible to participate?

Men and women:

- Between 18 and 75 years of age
- Who have been diagnosed with active moderate-to-severe ulcerative colitis or Crohn's disease
- Who are intolerant or non-responsive to standard therapies

What can I expect if I participate?

You would be scheduled for a screening visit to determine if you are eligible for the study. If you are eligible and decide to participate, you would receive 10 treatment visits over 9 weeks, and 4 follow-up appointments. The study lasts 24 weeks.

Eligible study participants will receive, at no charge, all study-related:

- Physical exams
- Laboratory tests
- Disease assessments

Two out of three participants will receive the investigational therapy, and one out of three will receive a sham/placebo apheresis procedure. Most study participants can remain on their current treatment regimen.

To find out if you may be eligible to participate in these clinical research studies please call (toll free)

1-866-560-5828

or e-mail Adacolumn@robarts.ca

A research study
for IBD therapy

starts here

CAUTION: Investigational device. Limited by U.S. Federal law to investigational use.

