Health Matters
The Center for Pharmaceutical Research
Excellence Since 1986
Winter 2007

Arthritis Explained

By John E. Ervin, MD, FACP, FACR

Arthritis . . . what image does this bring to your mind? The grandmother with painful hands who after taking Bayer aspirin can now frolic with her grandchildren and perform the tasks of gardening painlessly? Or perhaps someone with severe crippling who is wheelchair-bound?

Arthritis means many things to many people, and often one has misconceptions or no concept at all about what arthritis really is. Over 40 million people are affected by at least one of the conditions in the arthritis family of over 110 separate diseases. So, just what is arthritis?

We can divide the arthritic conditions into two major categories: inflammatory and non-inflammatory. The non-inflammatory group includes conditions such as fibromyalgia, others we categorize as soft tissue rheumatism, and osteoarthritis (also called wear-and-tear or degenerative arthritis). One half of all persons with arthritis have osteoarthritis (OA). Most of us will get some degree of OA with aging. There are two forms: the primary (or hereditary) form which affects mainly the hands and neck, and the secondary form affecting the weight-bearing joints, caused by excessive wear and tear (such as occurs with football players' knees, obesity or poor posture). Medications can ease the pain and stiffness of osteoarthritis, but it is more important to decrease the wear and tear causing the arthritis by means of weight reduction, posture correction and change in activities. For example, reducing one's weight by 10 pounds reduces the pressure on the knee by 60 pounds and in the hip by 70 pounds.

The inflammatory group includes about 100 different diseases including rheumatoid arthritis, gout, lupus, ankylosing spondylitis, Reiter's disease, Lyme arthritis, and arthritis associated with psoriasis to name a few. There are also many other rarer, rather fascinating but sometimes life-threatening diseases, which fall into this family. The inflammation in some of these diseases is not confined to just the joints or muscles, but may also affect the skin, heart, kidneys, lungs, blood vessels, and even the brain. The inflammation usually results from a malfunction of our immune system causing an "auto-immune" attack on our own body parts. Early proper diagnosis and treatment is extremely important in this group.

Rheumatoid arthritis (RA), the most common disease in the inflammatory group, is potentially a crippler. Luckily, we are now able to control RA in the great majority of cases. Several new medications for RA have become available in the last few years and many more are now being researched. These newer drugs, and ones we have used for years, can potentially put RA into remission and halt the damage to the joints.

Arthritis. It is not so simple, but thanks to advances in research leading to new treatments, the outlook for all types of arthritis is improving.

Just Ask

Answers to the questions you always wanted to ask

Q: What is shingles and who should receive a shingles (Herpes Zoster) vaccine?

A: Shingles is a localized skin rash, often with blisters, that is caused by the same virus that causes chicken pox. Shingles usually results in a long-term, extremely painful condition called postherpetic neuralgia. The Advisory Committee on Immunization Practices (ACIP) recommends that all persons 60 years of age and older receive the shingles vaccine.

Q: What causes pneumonia and how can I protect myself?

A: Pneumococcal disease (pneumonia) is caused by Streptococcus pneumoniae bacteria. Since about 1980, pneumonia vaccines have been available to adults over age 65. This vaccine has helped to prevent this common infection. Studies are now being conducted in populations under the age of 65 to further control the spread of this condition.

If you have a question regarding clinical research, please email us at es@ervinmd.com. Questions and answers may be printed in our next newsletter.

Poblano Corn Chowder with Shrimp

4 tablespoons (1/2 stick) butter, room temperature
2 tablespoons all purpose flour
1 medium onion, coarsely chopped
3 celery stalks, coarsely chopped
2 large poblano chilies,* seeded, chopped
2 14 3/4- to 15-ounce cans cream-style corn
1 16-ounce package frozen corn kernels, thawed
2 14-ounce cans low-salt chicken broth
1 cup whipping cream
2 teaspoons sugar
1/2 teaspoon cayenne pepper
1 pound uncooked shrimp, peeled, deveined, coarsely chopped
6 tablespoons chopped fresh cilantro

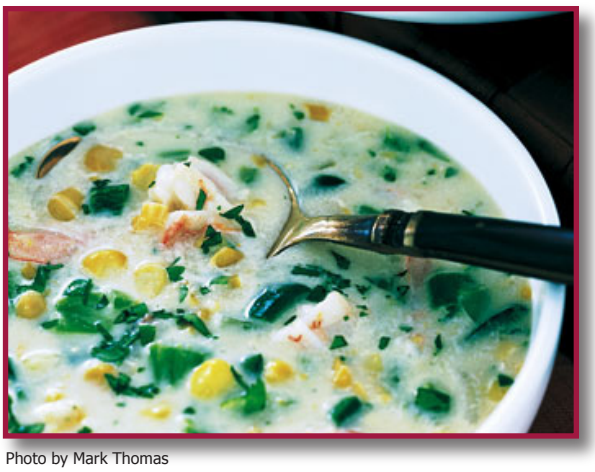

Photo by Mark Thomas

Mix 2 tablespoons butter and flour in small bowl to blend; set aside.

Finely chop onion and celery in processor. Melt 2 tablespoons butter in large pot over medium-high heat. Add onion-celery mixture and chilies; sauté until soft, about 6 minutes. Add creamed corn and next 5 ingredients; bring to boil. Reduce heat. Whisk in butter-flour mixture and simmer 15 minutes to blend flavors. Add shrimp and 4 tablespoons cilantro; simmer until shrimp are cooked through, about 5 minutes longer. Season with salt and pepper.

Ladle chowder into bowls. Sprinkle with remaining 2 tablespoons cilantro.

* Fresh green chilies, often called pasillas; available at Latin American markets and some supermarkets.

http://www.epicurious.com/recipes/food/views/107062

How to Choose a Clinical Trial

By John E. Ervin, MD, FACP, FACR

How a Drug Comes to Market

Before a drug is studied in human subjects it first must undergo extensive studies in the pre-clinical or laboratory phase. This involves years of experiments with human and animal cells, testing for toxicity, or any evidence that the drug causes tumor or cancer cells to develop. There is further, more extensive testing with animals in this phase. If the drug is found to be safe, this data is presented to the FDA, and a request for approval to begin testing the drug in humans is made. This is called an Investigational New Drug application (IND).

The clinical research testing of a new drug is done in three phases before being ready for consideration for FDA approval.

Phase I: These studies are primarily concerned with testing the drug's safety in human volunteers. This initial phase of testing in humans is done in a small number of healthy volunteers (20 to 100), who are usually paid for participating in the study. About 70 percent of experimental drugs pass this initial phase of testing.

Phase II: Once a drug has been shown to be safe, the next step is testing for effectiveness. This phase lasts from several months to two years. It involves up to several hundred patients. Most of these trials are randomized, i.e. the patients are randomly assigned (similar to flipping a coin) to a "control" group who will receive a placebo (sugar pill). The outcomes of this group are compared to the group receiving research medication. Phase II studies are also typically "blinded," meaning neither the patient nor the physician knows to which group the patient has been assigned. This is done to remove any bias the patient or the physician might subconsciously develop in assessing the patient's response to treatment, including any reported benefit, lack of benefit or side effects. Only about one-third of experimental drugs successfully complete both phase I and phase II studies.

Phase III: This is the final step before the research medication receives (or fails to receive) FDA approval for marketing and sale to the general public. The drug

is tested in several hundred to several thousand patients in this phase. This provides the pharmaceutical company with a more thorough understanding of the drug's effectiveness, benefits, and the range of possible adverse reactions. Most phase III studies are also randomized and double-blinded trials. They typically last several years.

If the drug receives FDA approval it may then go through additional testing in late Phase III or Phase IV trials. This further testing has several objectives:

- To compare a drug with other drugs already in the market.
- To monitor a drug's long-term effectiveness & impact on a patient's quality of life.
- To determine the cost-effectiveness of a drug therapy relative to other traditional and new therapies.

What Makes a Good Investigational Site?

A good study site should have the following characteristics and qualities:

- Trained personnel: Your coordinator should reflect knowledge of the study protocol and be able to answer any questions. If there are questions the coordinator cannot answer at the time, he/she should get back with you after getting the answer from the physician investigator, or, if necessary, from the pharmaceutical company sponsoring the study.

- Professional attitude: A careful, non-rushed consenting process with all your questions about the study being answered to your satisfaction should be conducted.

There are also some do's and don'ts that you should adhere to. You should always talk with the physician investigator before starting the study to ask any questions or address any concerns. He is ultimately responsible for every aspect of the conduct of the study at the site.

You should have a feeling of confidence that the staff places your interests and well being above that of the study itself. You should never have the feeling you are being pressured or coerced into doing the study. Do not get involved in a study just for the money, especially if it does not otherwise make sense to you. Read what you sign carefully; make sure any adverse events are explained, treatment-wise, by the pharmaceutical company. Understand the known potential side-effects of the study medication and its comparator drug. Placebo is often used in many trials; make sure you understand how this might affect your condition.

How Do Patients Benefit From Their Involvement in a Drug Study?

Most new investigational drugs coming out today are being developed in an effort to find better and/or safer medications compared to those presently on the market. They often, though not always, represent advances over those already in use.

The study volunteer usually receives expensive medications, exams, x-rays, and electrocardiograms at no cost; a huge benefit for an uninsured or poorly insured patient. Usually, the study patient also receives a stipend to recompense for travel and time.

In summary, investigational trials, when conducted properly, are usually very satisfying, safe and educational for the research volunteer. These volunteers often cite benefits of receiving state-of-the-art investigational medications and treatments that are otherwise not yet available. They also achieve an increased knowledge of their disease process, and obtaining medications free and treatment which

many, unfortunately, all too often can not afford.

Without research volunteers, there would be no research and no advances in the treatment of diseases. In the end, however, each individual must weigh all the factors in deciding if being a volunteer in a clinical investigational trial is right for him or her, and should choose their research site carefully.

Meet the Staff . . .

Linda Harding

Position:
Regulatory Coordinator

Professional Background:
11 years Administrative Asst.
13 years in bookkeeping
6 years Regulatory Coordinator

Favorite Hobbies:
Spending time with my granddaughter, Mikayla, shopping for bargains, and floral arranging

Favorite Part of my Job:
Pleasant work environment because of great co-workers

Favorite Memory at CPR:
Receiving the "Wall of Fame" award

What is a Regulatory Coordinator?

Clinical research is closely monitored and regulated by the Food and Drug Administration, or FDA. In addition, each study is monitored by an ethics committee called an Institutional Review Board, or IRB.

A Regulatory Coordinator completes and submits the appropriate documents to the IRB to ensure that the site is in compliance with both FDA and IRB guidelines.

the center for pharmaceutical research

"Tomorrow's medicines . . . Today!"

The Center for Pharmaceutical Research
1010 Carondelet Drive
Suite 426
Kansas City, MO 64114
816-943-0770

Make Your **Resolution** to Promote Medical Research

Volunteer for a Clinical Trial

The Center for Pharmaceutical Research is currently seeking volunteers to participate in the studies listed below. Study participants receive study related medication, laboratory tests, and exams at no cost. Compensation is also provided for time and travel. If you are interested in being considered for a study listed below, or in adding your name to our mailing list, please contact our Enrollment Services department at 816-943-0770 or es@ervinmd.com.

Study Condition	Compensation up to:
Osteoarthritis of the Knee (3 studies)	***up to $550***
Weight Loss for Type II Diabetics	***$840***
Pneumonia Vaccine	***$200***
Rheumatoid Arthritis (3 years)	***$1,300***
Shingles Vaccine	***$50***
Healthy Patient Vaccine Studies	***Varies***
Heavy Menstrual Cycle	***$900***

Future studies include: Oral Contraceptive, Obesity, Migraine, Fibromyalgia, Diabetes, Women's Health, Men's Health, High Blood Pressure, Alzheimer's Disease, Bird Flu Vaccine, Hepatitis B Vaccine, and other Vaccine studies.

Refer a friend who qualifies and receive $25-$50!

Health Matters
is published by
The Center for Pharmaceutical Research
1010 Carondelet Drive
Suite 426
Kansas City, MO 64114
816-943-0770

The information it contains is general in nature and should not be applied to self-diagnosis or treatments for any medical condition. Anyone who has, or suspects, a medical problem should consult a qualified physician. Please contact our office if you wish to be removed from our mailing list.

CPR

John E. Ervin, MD, FACP, FACR