Clinical Trial ID:

NCT00000404

Title:

Effects of Comprehensive Care for Knee OA

Summary:

We will study 300 people with knee osteoarthritis (OA) who receive their medical care from a large health maintenance organization (HMO) in Indianapolis. Our study will evaluate a comprehensive plan for treatment of knee OA by primary care physicians.

Primary care physicians will provide standard care for knee OA to half of the study participants (150 people), and will use the comprehensive treatment plan guidelines to treat the other half. The comprehensive plan includes careful use of medications along with non-drug approaches such as patient education, exercise, and social support. People who participate in the study will receive care for knee OA for 1 year. We will measure the results (outcomes) of treatment at the start of the study and at 3 months, 6 months, and 12 months after patients join the study. The results we will measure include joint

pain, physical function, drug side effects, quality of life, satisfaction with OA care,
and the cost of medical care.

Detailed Description:

Anticipating trends toward generalism in medicine, the rheumatology community has begun to set forth guidelines for managing osteoarthritis (OA). These guidelines emphasize a comprehensive approach toward nondrug treatment (e.g., patient education, exercise, social support) and a conservative approach to drug management to minimize the side effects of nonsteroidal anti-inflammatory drugs (NSAIDs). Unfortunately, few primary care physicians provide conservative, comprehensive care for OA as promoted in the recent rheumatology literature. Also, although researchers have studied individual elements of a comprehensive approach to OA care and largely validated them in isolation, no research support exists to suggest that uniformly adopting OA care guidelines will result in better patient outcomes and/or reduced costs of care.

In this project, we will implement, in a controlled fashion, and evaluate a comprehensive

plan for treating patients with knee OA by primary care physicians in a managed care environment. Comprehensive care for knee OA will be guided by a procedure designed to introduce and reinforce (a) an array of nondrug, self-care procedures intended to combat joint pain and preserve function and (b) a stepped protocol for drug management of knee pain that minimizes the risk of adverse side effects of NSAIDs.

Participants will be 300 patients with a confirmed clinical diagnosis of knee OA who receive their medical care in a large health maintenance organization (HMO) in Indianapolis, Indiana. We will randomly allocate geographically discrete offices of the HMOs to experimental (OA care by algorithm) or control (routine OA care) conditions (150 subjects/group). Patients who enroll in the study at each location will receive care for knee OA for 1 year under the guidelines specified by random assignment.

We will measure outcomes at baseline and 3 months, 6 months, and 12 months after enrollment, and outcomes will include joint pain, physical function, drug side effects,

quality of life (i.e., general health status), satisfaction with OA care, and direct costs of medical care. We think that comprehensive care, as guided by our algorithms, will result in significant improvement in knee pain, physical function, and patient satisfaction, and lower direct costs compared to care delivered under routine circumstances.

Eligibility Criteria:

Inclusion Criteria:

- **Study participants must be treated for chronic knee pain by a primary care physician at a participating HMO and satisfy American College of Rheumatology Clinical Criteria for the diagnosis of knee OA.**

- **All subjects will be able to read and write English, have a telephone, and give informed consent.**

Exclusion Criteria:

- **Significant hematologic, renal, hepatic, or cardiovascular disease (but not including mild/moderate hypertension) or any other serious medical condition that**

might preclude the subject's ability to participate fully in the project, keep clinic appointments, etc.

- Conditions other than knee OA which limit lower extremity function and mobility and/or would confound the evaluation of knee pain and function (e.g., clinically significant spinal or hip arthritis, painful or dysfunctional feet, peripheral vascular disease, lumbar radiculopathy, stroke, etc.).

- A known "secondary" cause of OA, including acute or chronic infectious arthritis; crystal-induced arthritis; systemic inflammatory connective tissue disease (e.g., rheumatoid arthritis, systemic lupus erythematosus); osteonecrosis; Paget's disease; or metabolic diseases, such as hemochromatosis, Wilson's disease, or ochronosis.

Gender:

All

Minimum Age:

40 Years

Maximum Age:

N/A

Phase:

Phase 2

Conditions:

- Osteoarthritis

Interventions:

- Patient education in self-care of knee OA

Locations:

- Long Hospital, Room 545, Indianapolis, Indiana