A Randomized, Controlled, Double-Blind Study of a Single Intra-Articular Injection of the less than 5,000 MW Fraction of Human Albumin 5% (Ampion-Trademark) in Adults with Osteoarthritis of the Knee

ACTRN12611000940976

Status	RECRUITING
Phase	Phase 1
Sponsor	Ampio Pharmaceuticals
Enrollment	60 participants

Plain Language Summary

This study is testing whether a single injection of a substance called Ampion directly into the knee joint can reduce pain and improve movement in people with knee osteoarthritis (wear-and-tear arthritis). Ampion is derived from human albumin (a natural protein in blood). Participants will receive one of three types of injections and will be followed for 4 days to check for effects and side effects.

You may be eligible if:
- You are between 40 and 85 years old
- You have been diagnosed with moderate knee osteoarthritis (Grade II or III) for at least 6 months
- You are able to walk independently
- You are able to give written informed consent
- You are willing to avoid pregnancy during the study (if applicable)

You may NOT be eligible if:
- You are pregnant or breastfeeding
- You have had a knee injection, surgery, or arthroscopy recently
- You have inflammatory arthritis, crystal arthritis, fracture, or severe bone loss
- You have a known allergy to human albumin
- You have been treated with steroids, anticoagulants, or NSAIDs recently

Talk to your doctor about whether this trial might be right for you.

Key Eligibility Criteria

Inclusion (7)

- Male or female, 40 years to 85 years old (inclusive), fully ambulatory, willing to sign informed consent.
- Symptomatic index knee osteoarthritis greater/equal to 6 months prior to screening with Kellgren Lawrence Grade II or III.
- Symptoms in the index knee for at least 6 months preceding screening.
- Because of the unknown effects of AmpionTM, women should avoid becoming pregnant during the course of this study if you become pregnant you will have to withdraw from the trial and your medical progress will be carefully followed. These precautions are necessary because the information on the effects on the unborn or new born baby of drugs like AmpionTM, is still very limited. Your own doctor, as well as the study coordinator should be able to assist you if you have any questions about the need to avoid pregnancy.
- Because of the unknown effects of AmpionTM, on sperm and possibly on foetus, men should avoid any possibility of fathering a child during the course of this trial. If your partner does become pregnant you should notify the study coordinator and their medical progress will be monitored. These precautions are necessary because the information on the effects on the unborn or new born baby of drugs like AmpionTM, is still limited. Your own doctor, as well as the study coordinator, should be able to assist you if you have any questions about the need to avoid emitting sperm that might result in pregnancy.

... and 2 more (see full listing online)

Exclusion (25)

- As a result of medical review and screening investigation (including electrocardiogram (ECG) and laboratory tests), the Principal Investigator considers the patient unfit for the study.
- A history of allergic reactions to excipients in 5% human albumin (N-acetyltryptophan, sodium caprylate).
- Any intra-articular or local periarticular injection, injection or surgery to the index knee during the 6 months prior to screening.
- Operative arthroscopy within 3 months of screening.
- Surgical procedure to the index knee other than arthroscopy within 12 months of participation in the trial.

... and 20 more (see full listing online)

Locations (1 total)

Australia