Trial record **1 of 1** for: Calosyn

Previous Study | Return to List | Next Study

Safety, Tolerability, and Efficacy of IA Verapamil in the Treatment of Joint Pain in Subjects With Osteoarthritis of the Knee

ClinicalTrials.gov Identifier: NCT01645709

Recruitment Status : Terminated (Sponsor decision to terminate study)
First Posted : July 20, 2012
Results First Posted : September 5, 2014
Last Update Posted : September 5, 2014

Sponsor:
Calosyn Pharma, Inc.

Collaborator:
Health Decisions

Information provided by (Responsible Party):
Calosyn Pharma, Inc.

Study Description

Go to

Brief Summary:

This is a randomized, double-blind, placebo-controlled, multi-center study to evaluate the safety, tolerability, and efficacy of Intra-Articular (IA) verapamil in the treatment of joint pain in patients with knee osteoarthritis (OA). Subjects will discontinue all analgesic medications for the entire duration of the study, except for acetaminophen (taken on an as needed basis at no more than 2 g/day). At visit 2, subjects who meet all entry criteria will be randomized to receive a single injection of IA verapamil or IA placebo at a ratio of 1:1. Treatments will be given with fluoroscopy or ultrasound to confirm needle placement. Subjects will be monitored for blood pressure and heart rate (sitting and standing) for at least 1 hour post-injection. Subjects will be evaluated at weeks 1, 2, 3, 4, 6, 8, and 12 after treatment.

Condition or disease	Intervention/treatment	Phase
Osteoarthritis of the Knee	Drug: Verapamil Drug: Placebo	Phase 1 Phase 2

Study Design

Go to

Study Type :	Interventional (Clinical Trial)
Actual Enrollment :	81 participants
Allocation:	Randomized
Intervention Model:	Single Group Assignment
Masking:	Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)
Primary Purpose:	Treatment
Official Title:	CS-201: A Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Safety, Tolerability, and Efficacy of Intra-Articular Verapamil in the Treatment of JoinT Pain in Subjects With Osteoarthritis of the Knee
Study Start Date :	April 2012
Actual Primary Completion Date :	February 2013

Resource links provided by the National Library of Medicine NIH NLM

Genetics Home Reference related topics: Osteoarthritis

MedlinePlus related topics: Osteoarthritis

U.S. FDA Resources

Arms and Interventions

Go to

Arm	Intervention/treatment
Experimental: Verapamil Subjects will be randomized to receive a single injection of IA Verapamil or IA Placebo at a ratio of 1:1.	Drug: Verapamil
Placebo Comparator: Placebo Subjects will be randomized to receive a single injection of IA Verapamil or IA Placebo at a ratio of 1:1.	Drug: Placebo

Outcome Measures

Go to

Primary Outcome Measures :

1. Compare Efficacy of Verapmil vs Placebo at Week 4 [Time Frame: 4 weeks]

   To compare the efficacy of IA verapamil versus IA placebo for pain relief using the Western Ontario and McMaster Universities Arthritis Index (WOMAC) at week 4.

Secondary Outcome Measures :

1. Compare Efficacy of Verapamil to Placebo Compared to Baseline [Time Frame: 13 weeks]

To compare the efficacy of IA verapamil and IA placebo using change from baseline in the following:

• WOMAC total and subscale scores for pain, function, and stiffness at each visit

2. Compare Efficacy of Verapamil to Placebo Compared to Baseline [Time Frame: 13 weeks]

To compare the efficacy of IA verapamil and IA placebo using change from baseline in the following:

• WOMAC pain subscale as measured from 2 to 12 weeks post-treatment using an AUC approach

3. Compare Efficacy of Verapamil to Placebo Compared to Baseline [Time Frame: 13 weeks]

To compare the efficacy of IA verapamil and IA placebo using change from baseline in the following:

• In-clinic 24-hour recall pain intensity using the 0-10 numerical rating scale (NRS) at each visit

4. Compare Efficacy of Verapamil to Placebo Compared to Baseline [Time Frame: 13 weeks]

To compare the efficacy of IA verapamil and IA placebo using change from baseline in the following:

• Difference in the current in-clinic pain intensity using the 0-10 NRS before and after exercise at each visit

5. Compare Efficacy of Verapamil to Placebo Compared to Baseline [Time Frame: 13 weeks]

To compare the efficacy of IA verapamil and IA placebo using change from baseline in the following:

• Response rate

6. Compare Efficacy of Verapamil to Placebo Compared to Baseline [Time Frame: 13 weeks]

To compare the efficacy of IA verapamil and IA placebo using change from baseline in the following:

• Patient Global Impression of Change (PGIC)

7. Compare Efficacy of Verapamil to Placebo Compared to Baseline [Time Frame: 13 weeks]

To compare the efficacy of IA verapamil and IA placebo using change from baseline in the following:

• Rescue medication use

8. Number of Subjects With Adverse Events [Time Frame: 13 weeks]

Compare the safety of IA verapamil versus IA placebo using adverse events (AEs) as a comparator

Eligibility Criteria

Go to

Information from the National Library of Medicine

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the contacts provided below. For general information, Learn About Clinical Studies.

Ages Eligible for Study:	35 Years to 75 Years (Adult, Older Adult)
Sexes Eligible for Study:	All
Accepts Healthy Volunteers:	Yes

Criteria

Inclusion Criteria:

Subjects must meet all of the following inclusion criteria to participate in the study:

1. Be 35-75 years of age and in good general medical and psychological health.
2. Be able to speak, read, write, and understand English, understand the consent form, complete study-related procedures, and communicate with the study staff.

3. Have OA of at least 1 knee (target knee) for at least 6 months and meet all the following criteria:
    - OA documented by standing X-rays anterior-posterior patella-femoral view taken within 1 month of screening visit indicating Kellgren-Lawrence Grade 2 to early-stage Grade 4 radiographic stage of the knee;
    - Have pain associated with OA of the target knee for at least 25 of the last 30 days; c. Meet the American College of Rheumatology clinical classification criteria, defined as having pain in the target knee and at least 3 of the following 6 items:
        - Age > 50;
        - Morning stiffness <30 minutes;
        - Crepitus on active motion;
        - Bony tenderness;
        - Bony enlargement;
        - No palpable warmth of synovium.
4. Target knee does not have any type of orthopedic and/or prosthetic device.
5. Based on standard physical examination of the target knee, does not have any neurovascular deficits, any skin abnormalities, any meniscal abnormalities, or any ligament instability.
6. At treatment visit 2 prior to randomization, have a score of at least 20 on the WOMAC pain subscale (questions 1-5) for the target knee and an in-clinic average pain intensity score of at least 4/10 on the 0-10 NRS for the 24-hour recall.
7. Be willing to maintain any present stable treatment modalities (e.g., acupuncture or physical therapy) and be willing to refrain from initiating any new treatment modalities.
8. Be willing to stop taking nonsteroidal anti-inflammatory drugs (NSAIDs) and opioids for the duration of the study.
9. If female of child-bearing potential (ie, not medically or surgically sterilized or not post-menopausal more than 1 year) or fertile male with sexual partner of childbearing potential, be willing to use adequate and reliable contraception throughout the study (eg, abstinence or barrier with additional spermicidal foam or jelly, or the use of intrauterine device or hormonal contraception by female subjects and partners of male subjects).
10. Not be enrolled in any other clinical trial and not have used any investigational drug within 1 month.

Exclusion Criteria:

Subjects who meet any of the following criteria will not be eligible to participate:

1. Have a Kellgren-Lawrence Grade 1 radiographic stage of the knee or have Kellgren-Lawrence Grade 4 radiographic end stage of the knee with bone on bone, ie, less than 2 mm joint space.
2. Be a candidate for knee replacement within next 6 months.
3. Have a body mass index > 35 kg/m2.
4. Have a Hospital Anxiety and Depression Scale score >12 on either subscale or have an established history of major depressive disorder not controlled with medication.
5. Have, in the Investigator's opinion, clinically significant abnormalities in clinical laboratory tests (hematology, clinical labs, urinalysis).
6. Have a positive urine drug test for illegal drug substances at screening.
7. Have, in the Investigator's opinion, clinically significant abnormalities in electrocardiogram readings
8. If a female of childbearing potential, have a positive pregnancy test at screening.
9. Have significant pain outside the target knee, including significant hip or back pain (bilateral knee OA will be allowed as long as target knee pain can be distinguished from contralateral knee pain and contralateral knee does not require treatment).
10. Have pain affecting the target knee that is due to any etiology other than OA.
11. Have documented history of inflammatory arthritis, including rheumatoid arthritis.
12. Have a meniscal tear in the target knee.
13. Have had viscosupplementation with hyaluronic acid products within 6 months prior to screening.
14. Have failed to respond to prior treatment with viscosupplementation with hyaluronic acid products.
15. Have had IA corticosteroid injections within 12 weeks or intramuscular or oral steroids within 4 weeks prior to screening.
16. Have had surgery of the target knee within 6 months prior to screening.
17. Have used opioids 4 or more days per week during in the past month prior to screening.
18. Are allergic to, or intolerant of, acetaminophen.
19. Have used verapamil within the past 4 weeks or are allergic or intolerant to verapamil.

Contacts and Locations

Go to

No Contacts or Locations Provided

More Information

Go to

Responsible Party:	Calosyn Pharma, Inc.
ClinicalTrials.gov Identifier:	NCT01645709 History of Changes
Other Study ID Numbers:	CS-201
First Posted:	July 20, 2012 Key Record Dates
Results First Posted:	September 5, 2014
Last Update Posted:	September 5, 2014
Last Verified:	August 2014

Additional relevant MeSH terms:

Osteoarthritis
Osteoarthritis, Knee
Arthralgia
Arthritis
Joint Diseases
Musculoskeletal Diseases
Rheumatic Diseases
Pain
Neurologic Manifestations
Nervous System Diseases
Signs and Symptoms
Verapamil
Anti-Arrhythmia Agents
Calcium Channel Blockers
Membrane Transport Modulators
Molecular Mechanisms of Pharmacological Action
Vasodilator Agents