The Safety and Efficacy of Single IA-HA Injection in Patients With Knee Osteoarthritis: A Prospective Study

ClinicalTrials.gov Identifier: NCT04577521

Recruitment Status : Completed
First Posted : October 8, 2020
Last Update Posted : October 14, 2020

Sponsor:
Goztepe Training and Research Hospital

Information provided by (Responsible Party):
Esat UYGUR, Goztepe Training and Research Hospital

Study Description

Brief Summary:
This prospective study was planned to carried out among the patients with grade II and III (Kellgren Lawrence classification) osteoarthritis of the knee attending outpatients clinic to evaluate the effectiveness and safety of viscosupplementation with intra-articular hyaluronic acid injection.

Condition or disease	Intervention/treatment
Gonarthrosis	Device: BioVisc Ortho Single

Detailed Description:
The study was designed as prospective, single-center, single-arm, open-label, observational study. The patients with grade II and III (Kellgren Lawrence classification) osteoarthritis of the knee attending outpatients were planned to enroll the study. Patients between the age 18-80 years who did not achieve remission of pain despite receiving the first-line treatment for gonarthrosis including nonsteroidal anti-inflammatory drugs medication, activity modification and ice, were planned to included in the study. A single dose of HA will be injected into the target knee joint. Clinical evaluation will be done using the Western Ontario and McMaster Universities Arthritis Index (WOMAC) and the short form-36 questionnaires (SF-36 v2) at baseline, 3 months and 6 months by a clinical secretariat.

Study Design

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Study Type :
Observational

Actual Enrollment :
67 participants

Observational Model:
Cohort

Time Perspective:
Prospective

Official Title:
Prospective Single Centre Open Label Investigator Initiated Clinical Study to Evaluate the Efficacy and Safety of Cross-linked Intra-Articular Hyaluronic Acid (HA)(Biovisc Ortho Single) in Patients With Knee Osteoarthritis (OA)

Actual Study Start Date :
March 4, 2019

Actual Primary Completion Date :
January 29, 2020

Actual Study Completion Date :
January 29, 2020

Resource links provided by the National Library of Medicine

MedlinePlus Genetics related topics: Osteoarthritis

MedlinePlus related topics: Osteoarthritis

Genetic and Rare Diseases Information Center resources:
Oculocerebral Syndrome With Hypopigmentation

U.S. FDA Resources

Groups and Cohorts

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Intervention Details:

- Device: BioVisc Ortho Single

  BioVisc Ortho Single consisted of a prefilled syringe containing 90 mg/3 mL of IA-HA and is an injectable-grade HA from a biofermentation origin. Biovisc ortho single prefilled syringes are intended for single-use only, and the entire content of the syringe was injected into the target joint.

Outcome Measures

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Primary Outcome Measures :

1. Change from Baseline to 3 Months and 6 Months in Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) [Time Frame: Baseline, 3 Months and 6 Months]

   WOMAC is health status measure questionnaire of twenty-four questions comprising 3 subscales (pain, stiffness and physical function). WOMAC was measured on a scale of 0-100 mm, where lower score represents lower pain and higher score represents higher pain.

2. Overview of Adverse Events (AE) [Time Frame: Through study completion, an average of 6 Months]

   An AE could be any unfavorable and unintended symptom, sign, disease or condition, or test abnormality whether or not considered related to the investigational product. A serious adverse event (SAE was an AE resulting in any of the following outcomes or deemed significant for any other reason: death; initial or prolonged hospitalization; life-threatening experience (immediate risk of dying); persistent or significant disability/incapacity; congenital anomaly. Treatment-emergent AEs (TEAE): AEs that developed/worsened during the 'on treatment period' (from first dose of study device until the end of study period). Category "AE" included participant with both serious and non-serious AE.

Secondary Outcome Measures :

1. Change in quality of life measured by SF-36 questionnaire (Short Form Health Survey questionnaire) [Time Frame: Baseline,3 Months and 6 Months]

   36-Item Short Form Health Survey (SF-36) is a set of generic, coherent, and easily administered quality-of-life measures.each item is scored on a 0 to 100 range so that the lowest and highest possible scores are 0 and 100, respectively. Scores represent the percentage of total possible score achieved. Each item is scored on a 0 to 100 range so that the lowest and highest possible scores are 0 and 100, respectively. Scores represent the percentage of total possible score achieved.

Eligibility Criteria

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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:

18 Years and older (Adult, Older Adult)

Sexes Eligible for Study:

All

Accepts Healthy Volunteers:

No

Sampling Method:

Probability Sample

Study Population

The patients with grade II and III (Kellgren Lawrence classification) osteoarthritis of the knee attending outpatients clinic

Criteria

Inclusion Criteria:

- Patients Age should not be less than 18 years.

- Patients must be able to understand and follow the study procedures and must provide written informed consent.
- Radiologically Grade II or III osteoarthritis of knee according to the Kellgren and Lawrence classification.
- Mild to moderate documented diagnosis of knee osteoarthritis that fulfill the ACR (American College of Rheumatology) criteria.
- Patients with consistent symptoms (joint pain, crepitus, swelling, effusion alone or combination of these symptoms) of knee osteoarthritis for at least 3 months prior to screening. If bilateral knee pain is present, the more painful knee will be selected.
- Patients who are willing to discontinue all non-steroidal anti-inflammatory drugs (NSAIDs) or other analgesic medication taken for any condition, including their knee pain. However patients will be allowed to use only acetaminophen or aspirin as a rescue pain medication during the study period. The patients must abstain from medication use 24 hours prior to any study visit.

Exclusion Criteria:

- Patients with secondary osteoarthritis of the knee according to ACR criteria.
- Pregnant or lactating women, and women of childbearing potential not willing to use adequate contraception.
- Patients unable to stay in the study for 6 months, non- cooperating, not able to understand
- Patients having previously undergone surgery on target knee, including arthroscopy.
- Patients with neurological deficit in the lower extremities, with primary inflammatory joint disease, intra-articular tumours.
- Any severe systemic disease(s).
- Any significant osteoarthritis symptoms in other joints apart from the target knee which may require pharmacological treatment during the study.
- Patients who have received intra-articular hyaluronic acid within the previous 6 month and/or intra-articular steroids or articular lavage in the target knee within the previous 3 months prior to their inclusion in the study.
- Administration of glucosamine sulphate, chondroitin sulphate and diacerein within the 3 months prior to their inclusion in the study.
- History of allergy or hypersensitivity to hyaluronic acid.
- Participation in any clinical study in the last 3 months and any surgery scheduled in the next 8 months that can affect directly the result of the present study.

Contacts and Locations

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Information from the National Library of Medicine

To learn more about this study, you or your doctor may contact the study research staff using the contact information provided by the sponsor.

Please refer to this study by its ClinicalTrials.gov identifier (NCT number): ***NCT04577521***

Locations

Turkey

İstanbul Medeniyet University
Istanbul, Kadıköy, Turkey, 34732

Sponsors and Collaborators

Goztepe Training and Research Hospital

More Information

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Responsible Party:
Esat UYGUR, Assoc. Prof. MD, Goztepe Training and Research Hospital

ClinicalTrials.gov Identifier:
NCT04577521 History of Changes

Other Study ID Numbers:
001

First Posted:
October 8, 2020 Key Record Dates

Last Update Posted:
October 14, 2020

Last Verified:
October 2020

Individual Participant Data (IPD) Sharing Statement:

Plan to Share IPD:
Undecided

Studies a U.S. FDA-regulated Drug Product:

No

Studies a U.S. FDA-regulated Device Product:

No

Additional relevant MeSH terms:

Osteoarthritis

Osteoarthritis, Knee

Arthritis

Joint Diseases

Musculoskeletal Diseases

Rheumatic Diseases