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Clinical trial on the intra-articular efficacy of MD-Knee (collagen medical device-knee) versus sodium hyaluronate in patients with knee osteoarthritis

Submission date
12/01/2016

Recruitment status
No longer recruiting

Registration date
18/01/2016

Overall study status
Completed

Last Edited
31/03/2016

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
Osteoarthritis (OA) is the most common type of arthritis and affects millions of people worldwide. It occurs when the protective cartilage on the end of bones wears away. The bones then rub against one another, causing stiffness, pain and a reduction in the range of movement. OA most often affects the knee joint, and is the leading cause of knee replacement surgery worldwide. In recent years, a number of treatments have been developed, which are injected directly into the affected joint. One such product is sodium hyaluronate (ARTZ®), which contains a form of hyaluronic acid (a chemical naturally found in the joints). By injecting ARTZ® into space where the bones of the joint meet (intra-articular injection) it acts to cushion and protect the joint, helping to reduce pain and improve range of movement. MD-Knee is a new intra-articular injection which has been developed to help treat OA. It contains collagen (a common protein which plays an important role in the structure of skin, bone, tendons and cartilage) derived from pigs. This is designed to work by providing a natural “scaffolding” to support the knee joint. The aim of this study is to find out whether MD-Knee or sodium hyaluronate (ARTZ®) is more effective in the treatment of patients with knee OA.

Who can participate?
Adults over 40 years of age who are suffering from knee OA.

What does the study involve?
Participants are randomly allocated to one of two groups. Participants in the first group are treated using MD-Knee, which is injected into the joint space (intra-articular injection) at a dose of 4ml, once a week for a total of five weeks. Participants in the second group are treated using ARTZ®, which is given by intra-articular injection at a dose of 2.5ml, once a week for a total of five weeks. Participants in both groups complete a number of questionnaires and patient interviews at the start of the study and again three and six months after treatment, in order to measure their pain levels and whether their condition has improved.

What are the possible benefits and risks of participating?
Participants may benefit from an improvement to their condition, experiencing lower levels of pain and a better quality of life. There are no significant risks of taking part in this study as the treatments offered are already used in the treatment of the disease.

Where is the study run from?
U.O.S. San Pietro Fatebenefratelli Hospital Rheumatology (Italy)

When is the study starting and how long is it expected to run for?
April 2013 to May 2015

Who is funding the study?
Guna S.p.a. (Italy)

Who is the main contact?
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Contact information

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Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
MDG20121404

Study information

Scientific Title
A double blind randomized active-controlled clinical trial on the intra-articular use of MD-Knee versus sodium hyaluronate in patients with knee osteoarthritis

Acronym
JOINT

Study objectives
The aim of this study is to evaluate the use of collagen MD-Knee versus sodium hyaluronate (ARTZ®) in patients with knee OA.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ordine Ospedaliero di San Giovanni di Dio- Fatebenefratelli- Provincia di Religiosa di San Pietro (Rome), 13/12/2015, ref: 116/2012/C.B

Study design
Double-blind randomised active-controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet.

Health condition(s) or problem(s) studied
Osteoarthritis (OA)

Interventions
Participants are randomly allocated to one of two groups.

Group A: Participants are treated using MD-Knee (Guna S.p.a., Milan, Italy), administered via the intra-articular injection of two 2.0 ml ampules, once a week for a period of 5 consecutive weeks.

Group B: Participants are treated using ARTZ® (Seikagaku, Tokyo, Japan), administered via the intra-articular injection of one 2.5 ml ampoule of sodium hyaluronate (ARTZ®), once a week for a period of 5 consecutive weeks.

All participants are monitored for all parameters considered in the trial (lequesne knee index (LKI), visual analogue scale (VAS), acetaminophen consumption 1000mg, SF36 questionnaire and adverse events) at 1 month and 3 weeks (first follow-up) and 4 months and 3 weeks (second follow-up) after the end of the treatment.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
1. ARTZ (Sodium Hyaluronate Injection) 2. Collagen MD-Knee

Primary outcome measure
Clinical improvement of condition is measured using the lequesne knee index (LKI) score at baseline and 3 months.

Secondary outcome measures
1. Clinical improvement of condition is measured using the lequesne knee index (LKI) score at baseline and 6 months
2. Pain is measured using the visual analogue scale (VAS) at baseline, 3 and 6 months
3. Health status is measured using the Short Form (36) Health Survey (SF36) at baseline, 3 and 6 months
4. Pain Killer consumption is measured using a patient diary completed between baseline to 6 months
5. Rate of adverse events (AE) are determined through observation by the investigators and patient reporting using the electronic- Case Report Form (e-CRF) between baseline to 6 months

Overall study start date
18/04/2013

Completion date
08/05/2015

Eligibility

Key inclusion criteria
1. Ambulatory adult patients affected by knee OA
2. Diagnosis of OA according to the ARA (American Rheumatism Association) criteria
3. Ages 40 years or over
4. Score greater than 7.0 on the Lequesne Knee Index at baseline
5. Persistence of pain in the knee for at least the last three months
6. Radiological degree II-III according to the Kellgren-Lawrence scale
7. Patients able to comply with the study procedures

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
29 patients in Group A (MD-Knee) and 31 patients in Group B (ARTZ®) were enrolled.Women included in Group A were 86.2% and 64.5% in Group B; mean age was similar in both groups (approximately 69 years).

Key exclusion criteria
1. Presence of comorbidities (i.e. rheumatoid arthritis, spondyloarthritis, connective tissue disease, polymyalgia rheumatica, gout, Paget's disease, septic arthritis, fractures, osteonecrosis, and fibromyalgia)
2. Patients with skin or subcutaneous tissue infection in the area of the joint to be treated
3. Patients who had used oral, parenteral or intra-articular corticosteroids in the preceding three months
4. Patients taking topical analgesics that may interfere with the evaluation of the study
5. Patients on anticoagulant therapy or suffering from thrombocytopenia and/or coagulopathy
6. Patient with allergy to products of porcine origins

Date of first enrolment
02/05/2013

Date of final enrolment
03/04/2014

Locations

Countries of recruitment
Italy

Study participating centre
U.O.S. San Pietro Fatebenefratelli Hospital Rheumatology (U.O.S. Reumatologia Ospedale San Pietro Fatebenefratelli)
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Sponsor information

Organisation
Guna S.p.a.

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Sponsor type
Industry

Website
http://guna.com/it/

ROR
https://ror.org/04mg7be43

Funder(s)

Funder type
Industry

Funder Name
Guna S.p.a.

Results and Publications

Publication and dissemination plan
Planned publication in BMC Musculoskeletal Disorders journal.

Intention to publish date
30/06/2016

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	22/02/2016		Yes	No