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Evaluating the clinical effectiveness and safety of a hyaluronic acid gel (ABIO 32/18) after intra-articular injections in patients with knee osteoarthritis

Submission date
28/05/2026

Recruitment status
No longer recruiting

Registration date
04/06/2026

Overall study status
Completed

Last Edited
28/05/2026

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Arturo Di Cosmo

Contact details
Via Meucci 36, Ospedaletto
Pisa
Italy
56121
+39 (0)50 3154257
arturo.dicosmo@abiogen.it

Type(s)
Public

Contact name
Dr Angela Magera

Contact details
Via Meucci 36, Ospedaletto
Pisa

Italy
56121
+39 (0)50 3154224
angela.magera@abiogen.it

Type(s)
Principal investigator

Contact name
Prof Alberto Migliore

Contact details
Via Cassia 600
Roma
Italy
00189
+39 (0)6 33505802
reumafbf@libero.it

Additional identifiers

Study information

Scientific Title
Open-label, randomised, multicenter, prospective investigation to evaluate the clinical effectiveness and safety of a hyaluronic acid gel (ABIO 32/18) after intra-articular injections in patients with knee osteoarthritis

Acronym
MDIA/01

Study objectives
Primary objective:
1. To evaluate if ABIO 32/18 provides a significant reduction of the articular pain in the target knee, assessed by a 0-100 mm visual analogue scale (VAS), for up to 3 months after the start of the treatment (baseline)

Secondary objectives
1. To evaluate if the two treatment regimens of ABIO 32/18 provide significant reduction of the articular pain in the target knee, assessed by VAS, after a further period of 6 months
2. To assess pain reduction and duration of the benefits within the two treatment regimens
3. To assess if the two treatment regimens of ABIO 32/18 provide significant improvement in severity of symptoms and functional status by evaluating changes in Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) Likert Scale
4. To evaluate the Patient Global Assessment of the treatment with ABIO 32/18 by using a 5-point numeric scale
5. To evaluate the Clinician Global Assessment of the treatment with ABIO 32/18 by using a 5-point numeric scale
6. To evaluate the effects of the two treatment regimens of ABIO 32/18 on EuroQol 5-dimension 5-level version (EQ-5D-5L) (questionnaire + VAS) Quality of Life index

7. To evaluate the effects of the two treatment regimens of ABIO 32/18 in Knee Injury and Osteoarthritis Outcome Score (KOOS)
8. To evaluate concomitant analgesic consumption in terms of percentage of patients, duration (days) and daily dose
9. To evaluate the usability of ABIO 32/18
10. To evaluate the safety and tolerability of ABIO 32/18 following i.a. treatment in patients with knee OA

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 10/06/2019, Comitato Etico Lazio 1 (Circonvallazione Gianicolense, 87, Roma, 00152, Italy; +39 (0)649979822; comitatoetico.lazioarea1@policlinicoumberto1.it), ref: N.696

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Open (masking not used)

Control
Uncontrolled

Assignment
Parallel

Purpose
Treatment

Study type(s)

Health condition(s) or problem(s) studied
Knee osteoarthritis

Interventions
A randomization list was prepared by the sponsor using a validated software (SAS PLAN Procedure Version 9.2) and sent to CMO. Patients were randomly assigned in a 1:1 ratio to receive one i.a. injection of 2 ml of hyalronic acid or two i.a. injections of 2 ml of hyaluronic acid on the target knee in accordance with a pre-defined randomization scheme. Each patient included in the investigation was coded by the Investigator through a Screening number (a two-digit site number followed by a two-digit progressive number for each site). Eligible patients were sequentially assigned, at each site, at Visit 2 (baseline), Day 0, to a 4-digit randomization number, available as they present themselves for the investigation, starting from the lowest number provided at that site. The randomization number was progressively assigned from the randomization list and was associated to the treatment (one or two injections).

Group 1: one injection of 2 ml of hyaluronic acid (20 mg/ml) on the target knee
Group 2: two injections of 2 ml of hyaluronic acid (20 mg/ml), on the target knee, once a week, for 2 consecutive weeks.

The investigation was divided into two phases:
Phase A: up to 3 months from the start of treatment to assess the main clinical endpoint set at Day 90 and the other secondary endpoints
Phase B: extended follow-up of 6 months to assess the duration of the benefits

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
ABIO3218 (hyaluronic acid gel)

Primary outcome(s)
1. Knee pain at rest measured using VAS (0-100 mm) at baseline and Day 90 ± 7

Key secondary outcome(s)

Completion date
05/05/2022

Eligibility

Key inclusion criteria
1. Voluntarily given informed consent to investigation participation in writing encompassing consent to data recording and verification procedures
2. Male and female patients, aged 45 to 80 years (inclusive)
3. Patients affected by knee osteoarthritis, as defined by the American College of Rheumatology (ACR) clinical and radiographic criteria for OA of the knee, and meeting the following conditions:
3.1. Kellgren-Lawrence Grade 2 to 3 severity OA of the knee with the presence of osteophytes determined from X-rays of the knee obtained within 6 months from the screening visit; i.e., in the tibio-femoral compartment of the target knee with at least one osteophyte and measurable joint space, as diagnosed by standard X-rays (anterior-posterior view [weight-bearing extension or semi-flexion] and lateral). In the case that a patient had not a valid X-ray within 6 months prior to screening, the exam was to be performed during the screening period
3.2. Patients suffering from OA symptoms of the target knee for at least 6 months prior to the screening visit
4. Pain at rest in the target knee of at least 40 mm on a 0-100 mm VAS
5. Patients having discontinued use of all systemic analgesic/non-steroidal anti-inflammatory drug (NSAID) therapies prior to the screening visit and agreed not to resume them during the investigation. Note: Paracetamol was provided to patients as rescue medication
6. If female of childbearing potential, had to have a negative urine pregnancy test at the screening visit and use a reliable form of contraception for more than 1 month prior to screening and throughout the investigation. Note: to be considered females of non-childbearing potential, females had to be surgically sterile or postmenopausal as documented in medical history for at least 1 year

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
45 Years

Upper age limit
80 Years

Sex
All

Total final enrolment
55

Key exclusion criteria
1. Patients with osteoarthritis secondary to other articular diseases
2. Patients with rheumatoid arthritis or other systemic inflammatory process
3. Patients with presence of infections and/or skin diseases and/or skin wounds in the area of injection site
4. Patients having received:
4.1. Corticosteroids by systemic administration within 30 days prior to the screening visit
4.2. NSAIDs by systemic administration within 7 days prior to the screening visit
4.3. Intra-articular drugs within 30 days prior to the screening visit and/or intra-articular corticosteroids within 60 days prior to the screening visit
4.4. Chondroitinsulphate, glucosamine sulphate, diacereine, bisphosphonates or matrix metalloproteinase (MMP) inhibitors within 30 days prior to the screening visit
4.5. Viscosupplementation of the target knee within 6 months prior to the screening visit
4.6. Paracetamol in the 24 hours prior to the screening visit
4.7. Treatment with any other investigational product within 3 months prior to the screening visit
5. Patients receiving treatments or physical therapies which could interfere with either the local i.a. injection of the investigational device or the evaluations of investigation results
6. Patients having had any previous surgery in the target knee within 6 months prior to the screening visit, or any planned surgery throughout the duration of the investigation
7. Patients having had diagnostic or surgical knee arthroscopy, or knee lavage in the target knee in the 6 months prior to the screening visit
8. Known or suspected hypersensitivity to HA and/or paracetamol
9. Patients with body mass index (BMI) >40 kg/m2
10. Patients that were candidate for knee replacement within next 6 months
11. Patients with large intra-articular effusion of the target knee
12. Patients with significant pain outside the target knee, including significant hip or back pain
13. Patients with clinically significant valgus/varus deformities, ligamentous laxity, or meniscal instability as assessed by the Investigator
14. Patients with any musculoskeletal condition affecting the target knee that would impair assessment of the effectiveness in the target knee (e.g. Paget’s disease of bone)
15. Patients who had arthroplasty at the target knee at any time
16. Patients with presence of serious gastrointestinal, renal, hepatic, pulmonary, cardiovascular,

or neurological disease that could interfere with the outcome of the investigation or the patient' s ability to comply with investigation requirements;
17. Patients with a current malignancy or had treatment for a malignancy, except non-melanoma skin cancer, within the past 5 years
18. Patients with history of kidney failure or renal insufficiency (creatinine >2.0 mg/dl)
19. Patients with clinically significant abnormalities of laboratory parameters measured at the screening visit
20. Pregnant (positive urine test) or breastfeeding women, or planning to become pregnant during the investigation
21. Patients who were not able to comply with investigation procedures or who were likely to be noncompliant or uncooperative during the investigation according to the investigator's opinion

Date of first enrolment
31/10/2019

Date of final enrolment
02/08/2021

Locations

Countries of recruitment
Italy

Sponsor information

Organisation
Abiogen Pharma (Italy)

ROR
https://ror.org/03rkzne32

Funder(s)

Funder type

Funder Name
Abiogen Pharma S.p.A

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not expected to be made available