UNIVERSITA' DEGLI STUDI DI CATANZARO
"MAGNA GRÆCIA"

SCUOLA DI MEDICINA E CHIRURGIA
DIPARTIMENTO DI SCIENZE MEDICHE E CHIRURGICHE
AZIENDA OSPEDALIERA "MATER DOMINI"

Effectiveness of a Next-Generation High-Power Laser Treatment Combined with Intra-Articular Injection of Hyaluronic Acid (HA) and Physiotherapy in Reducing Pain in Patients with Hip Osteoarthritis: A Randomized Controlled Clinical Trial

Type of Research (Setting)

☒Single-center
☐Multicenter

Type of Research (Design)

☒Interventional study (RCT or similar)
☐Retrospective observational study
☐Prospective observational study
☐Cross-sectional observational study
☐Systematic literature review
☐Non-systematic literature review
☐Case series
☐Single case study
☐Proposal of new decision-making algorithms

Introduction

Osteoarthritis is one of the most common diseases of our time. It affects the entire joint and is characterized by progressive cartilage loss, subchondral bone erosion, and damage to muscles and ligaments. The hip is a ball-and-socket joint that plays a critical role in weight bearing. During standing, walking, and running, the hip joint is subjected to static and dynamic forces that predispose the femur and acetabulum to chronic wear. Hip osteoarthritis (OA) is the leading cause of musculoskeletal disability in developed countries and one of the most common causes of limitations in daily activities among the adult population.

NCT number 429/2021, 13/06/2025

Diagnosis of coxarthrosis is often clinical, although radiographic investigations are useful for confirming and monitoring disease progression. The most widely used radiographic grading system for OA is the Kellgren and Lawrence (K&L) scale, ranging from 0 to 4, with grades 2 or higher indicating radiographic OA. Higher K&L grades reflect greater joint space narrowing, osteophyte presence, and subchondral sclerosis. Notably, there can be significant discordance between symptoms and radiographic findings.

Management of coxarthrosis includes educational, behavioral, psychosocial, physiotherapeutic, pharmacological, and physical therapy interventions. Physiotherapy is a cornerstone of conservative treatment, showing considerable effects on pain and disability. Intra-articular treatments, particularly with hyaluronic acid (HA), are also effective for reducing pain and improving function.

In OA joints, pro-inflammatory cytokines and proteases disrupt HA synthesis, reducing synovial fluid viscoelasticity. Exogenous HA injections improve synovial viscosity.

Study Objectives

The primary outcome of this randomized controlled trial (RCT) is to assess the effectiveness of a combined treatment consisting of intra-articular HA injections, high-power laser therapy, and standard physiotherapy in improving hip function in patients with coxarthrosis. Secondary outcomes include pain reduction, changes in hip joint range of motion (ROM), strength of the hip flexor and extensor muscles, and disability related to the pathology.

Materials and Methods

Participants

Patients with hip osteoarthritis will be recruited at the Complex Operative Unit of Physical and Rehabilitation Medicine of the Mater Domini University Hospital of Catanzaro starting from January 2022.

Inclusion Criteria:

- Age >18 years
- Diagnosis of hip osteoarthritis (stage ≤ 3 according to Kellgren and Lawrence classification)
- Hip pain with Numeric Rating Scale (NRS) ≥ 4
- Body mass index <30 kg/m^2
- Patients willing to discontinue NSAIDs, opioids, corticosteroids, muscle relaxants, or any therapy that could interfere with study evaluations, and agree not to resume such therapies during the study period

Exclusion Criteria:
- Severe cognitive decline (Mini-Mental State Examination score <24) and/or inability to provide informed consent
- Concurrent treatment with anti-inflammatory drugs or rehabilitative therapies
- Rheumatoid arthritis
- Previous hip replacement
- Planned lower limb surgeries within 6 months
- Oral analgesic therapy, intra-articular injections, physiotherapy, and/or instrumental physical therapy within the past 30 days
- History of neurological or psychiatric disorders
- Hemorrhagic diathesis
- Pacemaker users
- Oncological diseases
- Pregnancy or breastfeeding
- History of epilepsy
- Ongoing infectious diseases

Only patients who sign the informed consent for personal data processing, after reading the written information and understanding both the written and oral explanations provided by study staff, will be included. Patients will also be informed of their rights in accordance with Article 7 of Legislative Decree 30/06/2003, No. 196 (Privacy Code).

Intervention
At baseline (T0), enrolled patients will be randomly allocated (1:1 ratio) into two treatment groups:

- Study Group: 2 ultrasound-guided weekly intra-articular injections with Hymovis Hyaluronic Acid (HYADD 4) 24mg/3ml, followed by 10 sessions of standard rehabilitative treatment (5 sessions/week for 2 weeks), consisting of passive and active kinesitherapy, stretching and strengthening exercises (45 minutes each), combined with 10 sessions of high-power laser therapy (5 sessions/week for 2 weeks) using Laserix Pro.

- Control Group: same protocol as the study group, except that the laser therapy will be replaced with 10 sessions of sham laser therapy using the same device.

Blinding
Patients and the physician responsible for outcome evaluations will be blinded to group allocation. The physiotherapist administering the intervention will not participate in the outcome assessment.

Primary Outcome
Harris Hip Score to assess hip functionality.

Secondary Outcomes

- Reduction of pain in the hip joint, assessed by the Numeric Rating Scale (NRS), with a score from 0 (no pain) to 10 (worst pain ever experienced).
- Improvement in hip joint range of motion (ROM) for:
  - Abduction and Adduction (Right and Left)
  - Flexion-Extension (Right and Left)
- Manual Muscle Testing (MMT) to evaluate lower limb muscle strength
- Balance and gait assessed by the Tinetti Scale
- Six-Minute Walking Test (6MWT) to evaluate performance
- Health-Related Quality of Life (HRQoL) measured by the EuroQol 5 Dimensions 3 Levels Index (EQ5D3L Index)

Time-Points

T0: Baseline
T1: End of treatment
T2: 3 months after the first visit
T3: 6 months after the first visit
T4: 12 months after baseline

Sample Size

For sample size calculation, a non-Gaussian distribution of variables was assumed, considering the difference in pain score reduction between the two groups as the primary outcome. Given the exceptional nature of the study, the total sample size will be 15 patients per group. Assuming a hypothetical dropout rate of 10%, 34 participants will be required (17 per group).

References

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INFORMED CONSENT FOR THE STUDY:

Efficacy of a combined rehabilitative treatment with intra-articular hyaluronic acid injection and high-power laser therapy in improving hip function in patients affected by coxarthrosis: a randomized controlled clinical trial.

I, the undersigned, _____

born in _____ on _____ and residing at _____, declare that I am aware of my medical condition (Coxarthrosis).

I have been offered participation in an experimental clinical study at the Physical Medicine and Rehabilitation Unit of the Mater Domini University-Hospital of Catanzaro, which involves combined treatment with intra-articular hyaluronic acid injection, high-power laser therapy, and physiotherapy. The actual usefulness of this treatment, the possible outcomes, expected benefits, potential complications and local and/or general side effects, as well as the possibility of failure have been clearly explained to me.

The treatment procedures have been illustrated to me, which include my random assignment to one of the treatment groups as follows:

a cycle of 2 ultrasound-guided injections at weekly intervals into the hip joint with Hyaluronic Acid, 10 sessions of standard rehabilitative treatment (5 sessions/week for 2 weeks) lasting 45

minutes each, followed by 10 concomitant sessions (5 sessions/week for 2 weeks) of laser therapy (20 minutes);

or

a cycle of 2 ultrasound-guided injections at weekly intervals into the hip joint with Hyaluronic Acid, 10 sessions of standard rehabilitative treatment (5 sessions/week for 2 weeks) lasting 45 minutes each, followed by 10 concomitant sessions (5 sessions/week for 2 weeks) of "sham" laser therapy (20 minutes), during which my clinical and functional conditions will also be evaluated.

Follow-up checks are also planned. During the consultation with the Medical and Physiotherapy Staff, I received all the explanations requested for a full understanding of the treatment and had sufficient time to reflect on the information received, so as to give informed consent. I declare that I am fully aware, that I have carefully read this document, and that I have understood every part and its meaning.

Consent is personal and cannot be delegated to family members.

The undersigned _____ declares to have received from Dr./Ms. _____ exhaustive, realistic, understandable, and clear information regarding the treatment and possible side effects and declares the willingness to participate in the study.

Read and signed _____

The Patient _____

The Doctor _____