Evaluation of safety and efficacy of *Urtica dioica* cataplasm in the Management of Osgood-Schlatter Disease in Young Athletes: A study protocol for randomized, double-blind, placebo controlled clinical trial

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Abstract

Background

Osgood-Schlatter disease (OSD) is a common cause of knee pain in young athletes, often requiring rest and standard care for symptom relief. *Urtica dioica*, a medicinal plant traditionally used for musculoskeletal conditions, may offer a natural alternative. This study aims to evaluate the clinical efficacy and safety of *Urtica dioica* cataplasm (UDC) for the management of OSD in comparison to standard care.

Methods

This is a single-center, phase II, randomized, double-blind, placebo-controlled clinical trial. A total of 180 young athletes diagnosed with OSD will be randomly assigned in a 1:1:1 ratio to receive either UDC, placebo, or standard care consisting of rest and vitamin D supplementation. Participants in the UDC and placebo groups will receive topically applied cataplasms twice weekly for six weeks. Functional outcomes will be assessed using the KOOS-Child questionnaire, encompassing five subscales: pain, symptoms, daily living activities, sports and recreation, and knee-related quality of life. Pain intensity will be measured using the Visual Analogue Scale (VAS). Assessments will be performed at baseline, at 6 weeks (end of intervention), and at 3 months post-treatment to evaluate both short- and mid-term effects. Adverse events will be recorded at each follow-up visit.

Discussion

This is the first randomized clinical trial to investigate the use of UDC in pediatric OSD management. It is hypothesized that UDC will improve knee function, reduce pain severity, and enhance quality of life in affected individuals. Furthermore, it may shorten the rest period required before returning to sports activities, providing a promising complementary option for young athletes. The outcomes of this study could support the integration of safe, plant-based therapeutics into pediatric musculoskeletal care.

Trial Registration

The trial is prospectively approved and registered by the Human Research Ethics Committee of the Faculty of Medicine of Sousse, Tunisia [CEFMSo_0061_2025, 28/05/2025] and registered at ClinicalTrials.gov under the identifier NCT07096037 (https://clinicaltrials.gov/study/NCT07096037, 30/07/2025).

Background

Osgood-Schlatter Disease (OSD) is a common musculoskeletal disorder observed predominantly in adolescents and young athletes undergoing rapid growth spurts (1). It is characterized by inflammation and irritation of the tibial tuberosity resulting from repetitive strain, physical overuse, or previous knee trauma (2). Clinically, it manifests as localized pain, swelling, and, in some cases, gait disturbances, which may progress to long-term functional impairment (3, 4). Epidemiological studies suggest a prevalence rate of 9.8%, with a higher incidence among males (3:1 ratio) (5).

The etiology of OSD remains multifactorial and incompletely understood. It is predominantly linked to the physiological imbalance during adolescence, where accelerated bone growth may surpass the adaptability of surrounding musculature and tendons. This discrepancy contributes to increased mechanical stress on the tibial tubercle, resulting in inflammation and microtrauma (6). Management strategies typically include rest, NSAIDs, physical therapy, and, rarely, surgical intervention (1, 2, 7). However, these treatments primarily aim to alleviate symptoms and inflammation without promoting tissue healing (1). Additionally, prolonged NSAID use in pediatric populations may induce adverse effects, including gastrointestinal disturbances and nephrotoxicity (8).

In recent years, interest has surged in the application of natural plant-based therapies for managing inflammatory and musculoskeletal conditions. Phytoconstituents such as flavonoids, polyphenols, and terpenoids have demonstrated significant anti-inflammatory, antioxidant, and analgesic properties (9, 10). Their potential to modulate key inflammatory mediators and oxidative stress suggests a promising role in OSD management. Nonetheless, scientific evidence regarding phytotherapy for OSD remains limited, with only a single case report documenting plant extract use in this context (11).

Urtica dioica, commonly known as stinging nettle, is a medicinal plant recognized for its broad pharmacological activity and traditional use in treating joint pain, arthritis, urinary disorders, and skin conditions (12). It is rich in bioactive compounds including polyphenols, flavonoids, vitamins, and minerals, which contribute to its potent anti-inflammatory and antioxidant effects (13, 14). Experimental data supports its ability to downregulate pro-inflammatory cytokines (e.g., TNF-α, IL-1β) and enzymes such as COX-2, while enhancing endogenous antioxidant defenses (15, 16). Importantly, U. dioica is associated with a favorable safety profile and low toxicity, making it a suitable candidate for pediatric use (17, 18).

Objective

The primary objective of this clinical trial is to evaluate the efficacy and safety of a topical *Urtica dioica* cataplasm in managing knee pain and functional limitations in athletic children diagnosed with Osgood-Schlatter Disease. To our knowledge, this is the first randomized trial to explore the therapeutic potential of *U. dioica* in this indication.

Materials and Methods

Aim of the study

The objective of this clinical trial is to evaluate the efficacy and safety of a topical *Urtica dioica* cataplasm in managing knee pain and functional limitations in athletic children diagnosed with Osgood-Schlatter Disease. Efficacy will be assessed through changes in knee pain using the Visual Analog Scale (VAS) and functional outcomes using the Knee Injury and Osteoarthritis Outcome Score (KOOS). The results are expected to provide preliminary evidence supporting the integration of phytotherapeutic approaches in pediatric musculoskeletal care.

Trial Design

This study is designed as a single-center, double-blind, parallel, prospective, randomized controlled clinical trial conducted at the Sports Complex of the Etoile Sportive du Sahel, Sousse, Tunisia. The total duration of the study is 12 weeks, comprising a 6-week intervention period followed by a 6-week post-treatment (washout) phase. Pain severity and functional outcomes will be assessed periodically throughout the study to evaluate both short- and long-term effects of the interventions. Additionally, the trial conduct will be monitored through regular review of data collection and participant compliance to ensure adherence to the study protocol. Any important modifications to the study protocol will be documented and submitted for approval to the relevant ethics committee before implementation. Once approved, these changes will be communicated promptly to all relevant parties, including study investigators, participating sites, and trial participants (when applicable). Written informed consent will be obtained from all participants' legal guardians prior to enrollment.

Participants and Interventions

Eligible participants will be identified through collaboration with team physicians and physical trainers at the Sports Complex. Information about the study will be distributed to families of registered youth athletes, and those expressing interest will be screened for eligibility by the study team.

A total of 180 male children, aged 7 to 15 years, diagnosed with Osgood-Schlatter Disease (OSD) based on clinical evaluation, will be enrolled and randomly assigned in a 1:1:1 ratio into three parallel groups:

- **UDC Group**: topical application of *Urtica dioica* cataplasm
- **Standard Care Group**: oral vitamin D supplementation and physical rest
- **Placebo Group**: topical application of a placebo cataplasm using *Beta vulgaris subsp. Cicla*

Random allocation will be concealed using sequentially numbered, opaque, sealed envelopes prepared by an independent third party not involved in participant enrollment or intervention delivery. Blinding will be maintained for participants and outcome assessors throughout the study, except in cases where a medical emergency requires unblinding.

Inclusion Criteria

- Healthy male children between 7 and 15 years of age
- Active in regular sports practice (e.g., football)
- Clinically confirmed diagnosis of OSD

Exclusion Criteria

- Known allergy to *Urtica dioica*
- Presence of dermatological conditions or lesions on the knees
- Recent use of anti-inflammatory medications
- History of immune or chronic inflammatory diseases
- Diagnosis of any other bone disorder

Group Interventions

- **UDC Group**: Participants will receive a warm *Urtica dioica* cataplasm applied topically on the affected knee, once daily for 60 minutes, three times per week (on alternate days) over a 6-week period.
- **Standard Care Group**: Participants will receive oral vitamin D (Sterogyl®, 3 drops daily for 1 month) combined with activity reduction as advised by their orthopedic specialist.
- **Placebo Group**: Participants will receive a placebo cataplasm prepared using *Beta vulgaris subsp. cicla*, matched in texture, color, and odor to the active treatment. The placebo is inert and safe for pediatric topical use.

Preparation and Application of the Cataplasm

Fresh leaves of *Urtica dioica* will be thoroughly washed, lightly steamed, and crushed. The plant material will then be wrapped in sterile gauze and applied directly to the anterior aspect of the knee. All preparation and application steps will be standardized to ensure consistency across treatment groups and to maintain blinding.

Study Procedures

Prior to randomization, demographic, nutritional, and medical histories will be collected. Participants will be instructed to avoid the use of any additional anti-inflammatory medications, physiotherapy sessions, herbal remedies, or topical treatments during the study period unless medically necessary. Any use of concomitant care will be recorded and monitored.

Participants will be randomized into one of the three intervention groups using a computer-generated sequence. The cataplasm applications will follow a fixed schedule (every other day), and participants will be closely monitored for compliance, clinical progress, and adverse events. In the event of any harm or adverse effects resulting from trial participation, medical care will be provided according to institutional policies. Functional assessment will be performed at baseline and at the end of the 6-week treatment period. The trial flow chart of the study is represented in Fig. 1. No interim analyses or formal stopping rules are planned; however, participants retain the right to withdraw from the study at any point, and investigators may discontinue participation in case of non-compliance or adverse reactions.

All interventions, including preparation and application of cataplasms, will be administered by trained clinical personnel (physiotherapists or nurses) under the supervision of a physician experienced in pediatric musculoskeletal care. Personnel involved in outcome assessments will be trained in the use of KOOS-Child and VAS scales to ensure consistency.

Personal information about potential and enrolled participants will be handled in accordance with applicable data protection laws and institutional policies. Participant information will be coded to protect identity and accessible only to authorized study personnel. Data sharing outside the study team will occur only in de-identified or aggregate form, ensuring confidentiality before, during, and after the trial.

Outcome Measures

Primary Outcome

- **Pain intensity**: measured using the Visual Analog Scale (VAS), a 10-cm line anchored by “no pain” (0) and “worst imaginable pain” (10). VAS scores will be recorded at each clinical visit during the intervention period.

Secondary Outcomes

- **Functional knee status**: assessed using the KOOS-Child questionnaire, covering five subscales (pain, symptoms, activities of daily living, sport/recreation function, and knee-related quality of life). Scores range from 0 (extreme dysfunction) to 100 (no symptoms). Assessments will be done at baseline and after 6 weeks.
- **Return to sport**: defined as the number of days post-treatment needed to resume regular athletic activity.

Safety Outcomes

- Adverse events (skin reactions, discomfort, or other clinical complaints) will be recorded systematically at each follow-up visit and assessed by the clinical team.

Ethical Considerations

This study protocol has been reviewed and approved by the Human Research Ethics Committee of the Faculty of Medicine, University of Sousse, Tunisia [CEFMSo_0061_2025, 28/05/2025]. The study will be conducted in accordance with the principles outlined in the Declaration of Helsinki. Given the minimal risk nature of the intervention, no independent Data Monitoring Committee (DMC) was established. Oversight and safety monitoring will be carried out by the study investigators in coordination with the ethics committee

Sample Size and Statistical Analysis

Assuming a significance level (α) of 0.05, and 80% power (1 − β), the total sample size required was calculated to be 159 participants. To account for a dropout rate of 10–15%, the final sample size was increased to 180 participants, with 60 participants per group.

Data will be analyzed using SPSS software (version 28.0, IBM Corp., NY, USA). Continuous variables will be expressed as mean ± standard deviation. Between-group comparisons will be performed using the independent t-test or Mann–Whitney U test, depending on the data distribution. A p-value of < 0.05 will be considered statistically significant.

All data will be recorded on case report forms and subsequently entered into a secure, access-restricted electronic database. Regular data audits will be performed to ensure accuracy and consistency.

All analyses will follow the intention-to-treat principle, whereby all randomized participants will be included in the group to which they were assigned, regardless of adherence or protocol deviations. Missing data will be handled according to the last observation. Sensitivity analyses will be conducted to assess the impact of missing data on study outcomes.

Study status and timeline

This study is currently ongoing. Participant recruitment started in September 2025 and is anticipated to be completed by September 2026. Data collection began concurrently in September 2025 and is scheduled to conclude within one year (by September 2026). No data analysis has been performed to date, and no results have yet been generated. The analysis phase will commence only after the completion of data collection, with study results expected to be then available.

Discussion

Osgood-Schlatter Disease (OSD) is recognized as a prevalent cause of anterior knee pain among adolescents engaged in physical activities, particularly during periods of rapid skeletal growth. The underlying pathology involves traction-induced microtrauma at the tibial tuberosity, leading to localized inflammation, swelling, and compromised knee function (19, 20). Current management strategies for OSD typically include physical rest, targeted physiotherapy, vitamin D supplementation, and non-steroidal anti-inflammatory drugs (NSAIDs) (21, 22). While conservative in nature, these approaches are not always effective, and persistent cases may require surgical intervention, generally postponed until

skeletal maturity (23). Moreover, prolonged NSAID use in pediatric populations is associated with undesirable adverse effects, underscoring the necessity for safer, evidence-based alternatives that promote recovery without systemic toxicity (24, 25).

The functional implications of OSD extend beyond localized pain, often disrupting the athletic participation and competitive trajectory of affected children (26). Such interruptions, particularly during formative years, may adversely impact not only physical conditioning but also psychological well-being, manifesting as frustration, anxiety, or diminished self-esteem (27, 28). These multidimensional challenges highlight the need for therapeutic interventions that ensure effective symptom relief while enabling a safe and timely return to physical activity (29).

Urtica dioica (commonly known as stinging nettle) has been traditionally employed in various ethnomedical systems for the management of inflammatory, rheumatologic, and musculoskeletal disorders (30, 31). Its pharmacological potential has been attributed to a complex phytochemical composition that includes polyphenols, flavonoids, carotenoids, sterols, and phenolic acids (32, 33). These constituents exert antioxidant, anti-inflammatory, and analgesic effects through the modulation of cytokine expression and oxidative stress pathways (34, 35). Several clinical investigations have demonstrated the efficacy of *U. dioica* in alleviating joint-related pain and improving physical function, particularly in patients with arthritis (30). A notable study by Randall et al. demonstrated significant symptom reduction in osteoarthritic patients using topically applied fresh nettle leaves, supporting the rationale for its local application (36).

Despite its potential, the stinging sensation induced by direct contact with fresh *U. dioica* leaves commonly known as the urtication response limits its direct use in certain populations, particularly children. The use of a cataplasm offers a pragmatic alternative, allowing for the controlled application of active compounds directly to the affected site, reducing systemic absorption and minimizing the risk of adverse effects. This localized approach may enhance both safety and efficacy, particularly in pediatric populations. Recent studies have confirmed that cataplasm-based interventions result in low systemic exposure and a reduced incidence of skin irritation (37).

To date, no clinical trials have evaluated the application of *U. dioica* cataplasm in OSD. This trial represents the first effort to systematically assess its clinical efficacy and safety in comparison to standard care and placebo in children with confirmed OSD. *Beta vulgaris subsp. cicla* (Swiss chard) was selected as the placebo comparator, due to its absence of topical anti-inflammatory or analgesic properties in current scientific literature and its physical similarity to *U. dioica*, thereby supporting effective blinding.

In this study, outcome measures were chosen to reflect both subjective and objective dimensions of patient recovery. The KOOS-Child questionnaire, specifically validated for pediatric musculoskeletal conditions, assesses pain, function, and quality of life through five subscales, providing a comprehensive evaluation of clinical outcomes (38). In parallel, the Visual Analog Scale (VAS) remains a widely accepted instrument for quantifying pain perception in children and adolescents (39).

This investigation aims to generate evidence on the potential of *Urtica dioica* cataplasm as a plant-based, well-tolerated, and non-invasive therapeutic option for managing OSD. By reducing pain and improving function, this intervention could support early reintegration into sports activities, mitigate the psychological burden associated with prolonged athletic withdrawal, and ultimately promote better musculoskeletal health during critical phases of development. The outcomes of this trial may provide important insights into the integration of phytotherapy within pediatric orthopedic care.

Abbreviations

OSD
Osgood-Schlatter disease
UDC
Urtica dioica cataplasm
KOOS
Knee injury and Osteoarthritis Outcome Score
VAS
Visual Analogue Scale
NSAIDs
Non-steroidal anti-inflammatory drugs

Declarations

Ethics approval and consent to participate

The trial was approved by the Human Research Ethics Committee of the Faculty of Medicine of Sousse, Tunisia [CEFMSo_0061_2025, 28/05/2025]. Written informed consent will be obtained from all participants' legal guardians prior to enrollment.

Availability of data and materials

The datasets used during the current study are available from the corresponding author on reasonable request. Results will be published in peer-reviewed journals and shared with participants upon request.

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None.

Competing interests

The authors declare that they have no competing interests.

Authors' contributions

H.N. contributed to the development of the clinical protocol, preparation of the Urtica dioica cataplasm, and drafting of the manuscript. **N.E.F.** participated in patient recruitment, clinical assessment, and data collection. **A.L.** contributed to the methodological design, randomization procedure, and statistical planning. **M.G.** assisted in clinical monitoring, follow-up assessments, and data management. **R.M.** contributed to laboratory analyses and quality control of the plant preparation. **A.B.** participated in participant evaluation, safety monitoring, and adverse-event reporting. **S.E.M.** contributed to the study conceptualization, data interpretation and critical revision of the manuscript for important intellectual content. **A.Z.** contributed to the study conceptualization, supervised the overall project, ensured regulatory and ethical compliance, and provided final approval of the manuscript.

All authors read and approved the final manuscript.

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Consent for publication

Not applicable.

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Figures

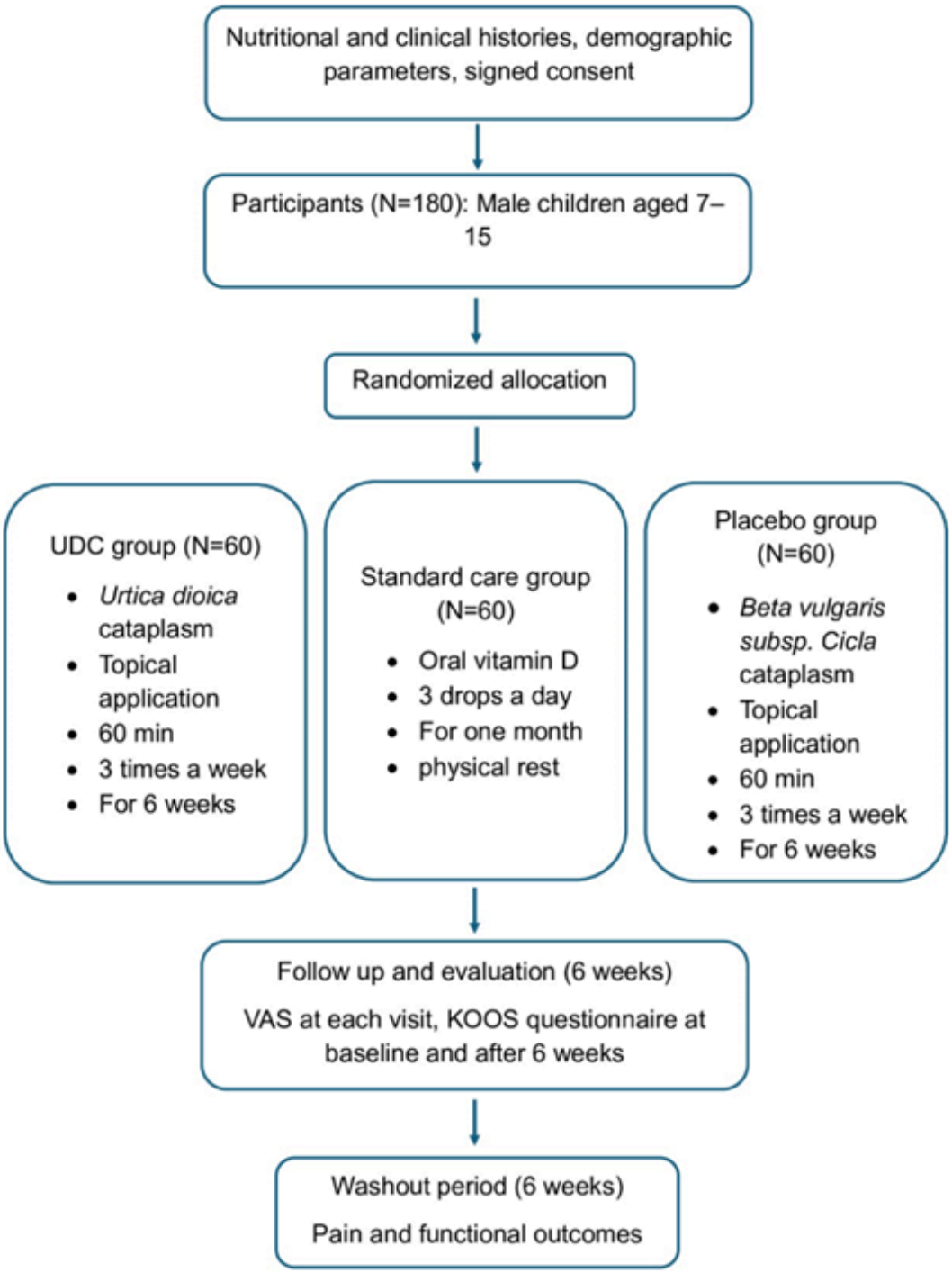

Figure 1

Flow chart of the study

Supplementary Files

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