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Casting and rehabilitation versus skillful neglect for osteochondral lesions of the talus in the pediatric population: the care study, a multicenter, prospective comparative study

T. M.F. Buck[1,2,3], F. Smithuis[2,3,6], J. A.H. Steman[1,2,3*], C. J.A. van Bergen[4,5], J. Dahmen[1,2,3], M. Terra[7], R. Hemke[2,3,6], Sjoerd A.S. Stufkens[1,2,3], M. Maas[2,3,6], Gino M.M.J. Kerkhoffs[1,2,3*] and P. A.A. Struijs[1,2,3]

Abstract

Background Skeletally immature osteochondral lesions of the talus (OLTs) have a significant impact on the health status and quality of life of pediatric patients and the involved family. the current literature showed success in 4 out of 10 patients but it is currently unknown which type of non-operative management showed better clinical- and radiological outcomes. The aim of this study is to compare immobilization and supervised rehabilitation with a 'skillful" neglect in the treatment for skeletally immature patients with an OLT. The hypothesis is that a period of immobilization and supervised rehabilitation will lead to better clinical and radiological outcomes compared to "skillful" neglect.

Methods Multicenter, prospective, comparative study. Skeletally immature children with an OLT will be assigned to the intervention or control group after a shared decision-making process. Patients in the intervention group will undergo a 4-week period of immobilization with normal casting and non-weightbearing, which is followed by 4 weeks of immobilization with a removable cast and weight bearing boot. Afterwards, they will receive a protocolled period of rehabilitation under supervision of a physical therapist. The control group will have a 'skillful" neglect treatment. The main study outcome is the difference between the two groups on the Oxford Ankle and Foot Questionnaire for Children (OxAFQ-C). Secondary study outcomes are radiologic changes in terms of morphology and lesion size. Numeric Rating Scale (NRS) during weight bearing and quality of life measured with a Pediatrics Quality of Life (Peds-QL) and EuroQol-5 Dimension youth (EQ-5D-y).

Discussion This protocol reports on the study design of the CARE Study and it aims to setup a study for evaluating different types of non-operative management in pediatric patients suffering an OLT. This study will compare clinical and radiological outcomes between two different non-operative strategies for treating OLTs in the skeletally immature

*Correspondence:
J. A.H. Steman
j.a.steman@amsterdamumc.nl
Gino M.M.J. Kerkhoffs
g.m.kerkhoffs@amsterdamumc.nl

Full list of author information is available at the end of the article

population. Based on the results of this study, an evidence-based treatment protocol for non-operative management for pediatric OLTs can be provided.

Trial registration This study is registered in the International Clinical Trial Registry Platform (ICTRP) with trial number NLOMON54282, date of registration 05192023.

Keywords Pediatric, Osteochondral lesion, Talus, Non-operative, Rehabilitation

Background

An osteochondral lesion of the talus (OLTs) can be congenital, posttraumatic or can occur in patients with juvenile idiopathic arthritis (JIA) [1–3]. Another hypothesis is that OLTs in the pediatric population are congenital and may be an incidental finding after trauma. The incidence of OLTs in the pediatric population is estimated to be 4.6 per 100,000, with patients aged 12–19 years representing the vast majority [4]. The main complaint of an OLT is pain during weightbearing activities [5]. Therefore, these lesions have significant impact on the health status of patients. To reduce the debilitating symptoms of patients with an OLT, adequate treatment of OLTs is essential. If inadequately treated, OLTs may also progress into osteoarthritis [6]. In this population, all patients start with any type of non-operative treatment. Adequate non-operative management may protect patients from surgery for their OLT and, subsequently, from an increased risk of early osteoarthritis. Additionally, adequate non-operative management may lead to a safe return to sport and radiological healing. Success rates of non-operative management for OLTs in literature range from 8 to 100% [7, 8]. This wide variation in success rate can partly be explained by the heterogeneity in study populations and wide variety on used non-operative strategies.

Non-operative management is frequently focused on "skillful" neglect till skeletally maturity has been reached. This means that patients are advised to alter their physical activities during their growing period. The "skillful" neglect strategy causes a decrease in physical possibilities which has major impact on the quality of life, and both the physical- and mental development of children. Another frequently used non-operative strategy is a period of immobilization and supervised rehabilitation [7].

Previous research on osteochondral lesions in the knee of skeletally immature patients has shown the potential of radiological healing at the end of the treatment and good clinical outcomes after a supervised immobilization- and rehabilitation protocol [9, 10]. Furthermore, previous research pointed out there is a significant relation between age and the success rate of non-operative treatment [11]. This study demonstrated that skeletally immature patients have a natural healing potential, in which an immobilization and supervised rehabilitation protocol can successfully support this potential. Healing of the lesion will likely resolve symptoms and therefore result in fewer physical restrictions which will improve clinical outcomes and thus the quality of life. However, the disadvantage of this strategy is that it can be considered intensive as patients will undergo a period of casting and the burden of visiting physical therapists for a long period.

Despite advantages and disadvantages of both treatment strategies, no comparison between the skillful neglect and standardized immobilization and supervised rehabilitation protocol in the non-operative management of OLTs of the ankle has been made in the current literature in the skeletally immature population. Additionally, little is known about return to sport and radiological outcomes for both strategies. Accordingly, a multicenter prospective comparative study will aid in directing the non-operative treatment towards an evidence-based approach, which could conceivably optimize the non-operative treatment strategy and improve the quality of life in young patients with an OLT.

Methods

Study design

For this multicenter prospective comparative study, two Dutch centers are involved: Amsterdam University Medical Centers, Location AMC, and Amphia Hospital Breda, the Netherlands. This study will be conducted in accordance with the Decleration of Helsinki. Approval was obtained from the local ethical board Medical Ethical Committee Amsterdam UMC (METC Amsterdam UMC, reference number NL78874.018.22).

Participants

All patients that present with an OLT, with open physes of the distal tibia on X-ray or CT are eligible for this study. There is no specific age range as skeletal maturity may be reached at different ages for each patient. The in- and exclusion criteria are shown in Table 1. Potential eligible patients will be seen at the outpatient clinic by the coordinating researcher or treating physician. If eligible patients visit our outpatient clinic, they, together with their caretakers will be informed about the purpose of our study. Both treatment regimens will be extensively explained. After explanation of the study, patients receive the Patient Information Folder (PIF). If patients

Table 1 In- and exclusion criteria. OLT = Osteochondral lesion of the talus

Inclusion criteria	*Exclusion criteria*
Symptomatic osteochondral lesion of the talus	Acute lesions
Diagnosed on Computed Tomography (CT)	Surgical treated OLT
Open physes of the distal tibia diagnosed on X-ray confirmed by a specialized musculoskeletal or pediatric radiologist	Systemic diseases that can influence cartilage conditions such as hemophilia and JIA

and their caretakers approve to participate in the study the Informed Consent form will be signed.

Shared decision making and treatment allocation

If patients and their caretakers sign the informed consent form and thereby agree to participate in the study, both treatment regimens and their pros and cons will be discussed. Hereafter, patients will be counselled for one of the two treatment regimens through a process of shared decision making, after which they are allocated to the group of the preferred regimen. The shared decision-making process is in a standardized format. This process includes the choice talk, option talk, and decision talk [12]. After the decision, patients will be placed in group one or two based on their preference. In the age group of < 12 years, caretakers will be decisive in the choice of treatment. In the group of 12–15 caretakers and patients both have to agree on the choice of treatment. In the group of > 16 years patients are themselves responsible in the choice of treatment, as patients > 16 years are considered an adult for medical decisions in the Netherlands.

Treatment groups

Intervention group

Patients in the first group will undergo a protocoled rehabilitation with the following phases:

- phase 1: a period of immobilization by use of a cast. The immobilization period consists of 8 weeks. 4 weeks in a circular cast with non-weightbearing followed by 4 weeks toe-tip weightbearing (10–20% of body weight) in a walking boot during daytime and a removable cast at night. All casts are applied in a standardized manner by specialized, 2-years trained, plaster technicians.
- phase 2: patients will return to activity under supervision of a physical therapist. The physical therapists will be instructed with information about what kind of activities are allowed, and what kind of activities need to be avoided. In case of clinical improvement after 16 weeks, patients will continue with phase 3.
- phase 3: in this phase, the rehabilitation is focused on return to sport. Dynamic exercises with an increasing impact and field training are allowed in a stepwise approach under supervision of a physical therapist.

An overview of the rehabilitation protocol is shown in Fig. 1.

Control group

Patients in the control group will undergo the "'skillful" neglect strategy which means that they adjust their activity level based on their complaints. Patients may perform all activities possible within the boundaries of pain, without peak force on the ankle joint. Based on the individual indication, patients will have physical therapy. As the amount of load that the ankle can withstand before complaints arise may differ per patient, there is no strict standardized protocol in this group. This in order to make the results best applicable to the clinical practice.

Physical therapy

After the confirmation of participation in the study, patients will be informed about the rehabilitation process. In order to support the treating physical therapists, they will be provided with a detailed protocol, which is outlined in Fig. 1. Patients will receive physical therapy from week 6 till the end of the study, two times a week.

Timeline

In Table 2, an overview gives an overview of all questionnaires administrated over time and radiologic follow-up executed within the time of the study.

Radiologic imaging consists of: patients will receive a weight-bearing X-ray (AP, lateral and mortise view) at baseline in order to classify their skeletal maturity, MRI and CT scans at baseline to provide a starting point in terms of radiologic characteristics and radiological follow-up at one year. At the time of all radiological imaging, physical consult will take place. At 26 weeks, patients will be approached by phone to fill in the digital questionnaires.

Clinical outcomes

Primary clinical outcome

The primary outcome is the group difference based on the Oxford Ankle Foot Questionnaire for Children (OxAFQ-C) at one-year follow-up. The OxAFQ-C is

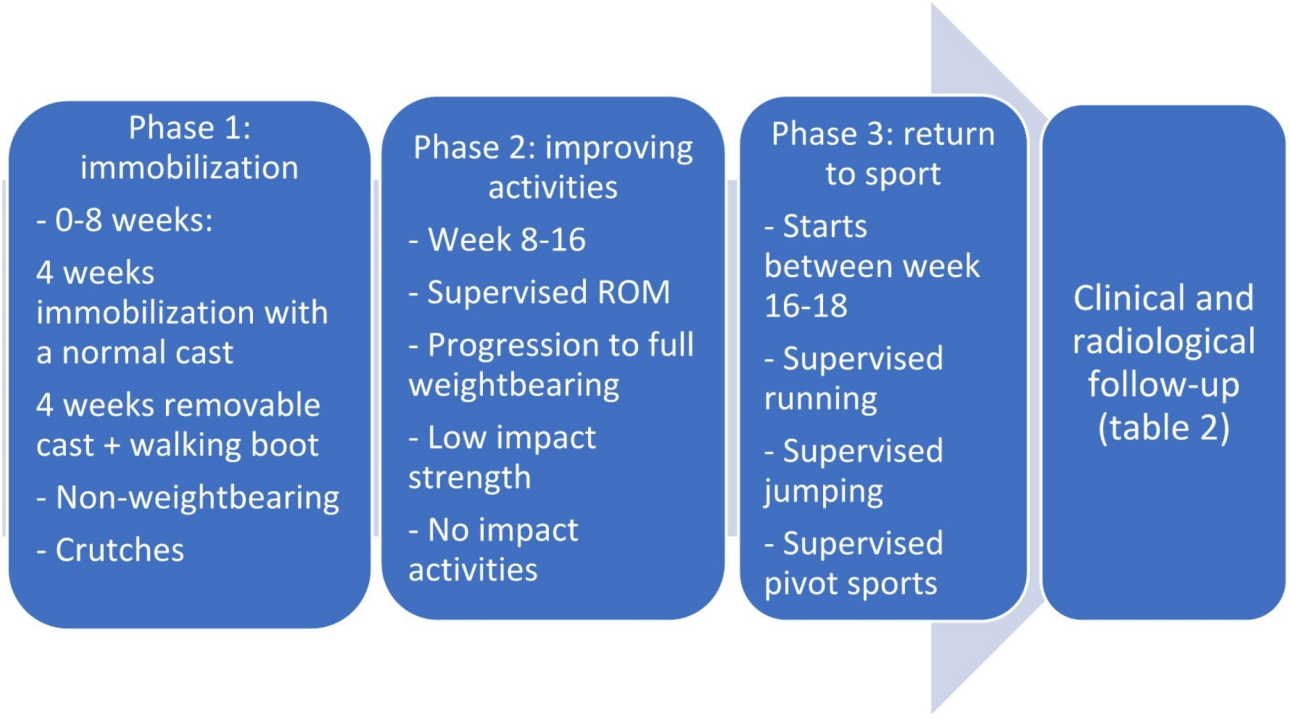

Fig. 1 Immobilization and supervised rehabilitation

Table 2 Clinical and radiological follow-up. MRI = Magnetic resonance imaging, wb = weightbearing, Ox-AFQ-C: Oxford ankle foot questionnaire for children, nrs = numeric rating scale, pedsql = pediatric quality of life inventory [13], EuroQol-5 dimension youth = EQ-5D-y

Follow-up moment	Clinical measurement	Radiological measurement
Baseline	Biographic information, history of sporting activities, NRS weightbearing, OxAFQ-C, PedsQL, Ankle Activity Score	X-ray, MRI, CT
16 weeks	Return to sport questions, NRS WB, OxAFQ-C, PedsQL, Ankle Activity Score	MRI, CT
26 weeks	Returning to sport questions, NRS WB, OxAFQ-C, PedsQL, EQ-5D-y, Ankle Activity Score	None
52 weeks	Returning to sport questions, NRS WB, OxAFQ-C, PedsQL, EQ-5D-y, Ankle Activity Score	MRI, CT

a specific child tailored questionnaire consisting of 15 points evaluating the subdomains ''physical'', ''school and play'', ''emotional'', and ''footwear'' with separate versions for children and parents [14].

Secondary clinical outcomes

Secondary study outcomes consist of the EuroQol-5 Dimension youth (EQ-5D-y), the Numeric Rating Scale (NRS) during weightbearing and return to sport outcomes. The number and severity of complications or adverse events will be recorded in the electronic patient files. The EQ-5d-y is a children tailored version of the adult EQ-5D and compromise the following subscales for measuring quality of life: mobility, selfcare, usual activities, pain/discomfort, and anxiety/depression [15]. The NRS is a 11-point scale which classify pain from 0 (no pain) to 10 (worst pain imaginable) [16]. Return to sport outcomes will be measured according to Ardern et al. [17] and will be classified in: return to lower-, same- or higher level of sports.

Radiological outcomes

Measurements on radiologic characteristics will be independently conducted by two specialized musculoskeletal radiologists at the moment of diagnosis. At the end of the study, all measurements will be assessed independently by two specialized musculoskeletal radiologists in order to increase the reliability of the measurements. Radiological characteristics that will be assessed at each radiologic follow up moment are the following:

- Lesion morphology (measured on CT) categorized as described in Fig. 2 [18].
- Lesion size (measured on CT): cranial-caudal (CC) diameter, medial-lateral (ML) diameter, anterior-posterior (AP) diameter, surface (ab π; CC x AP x

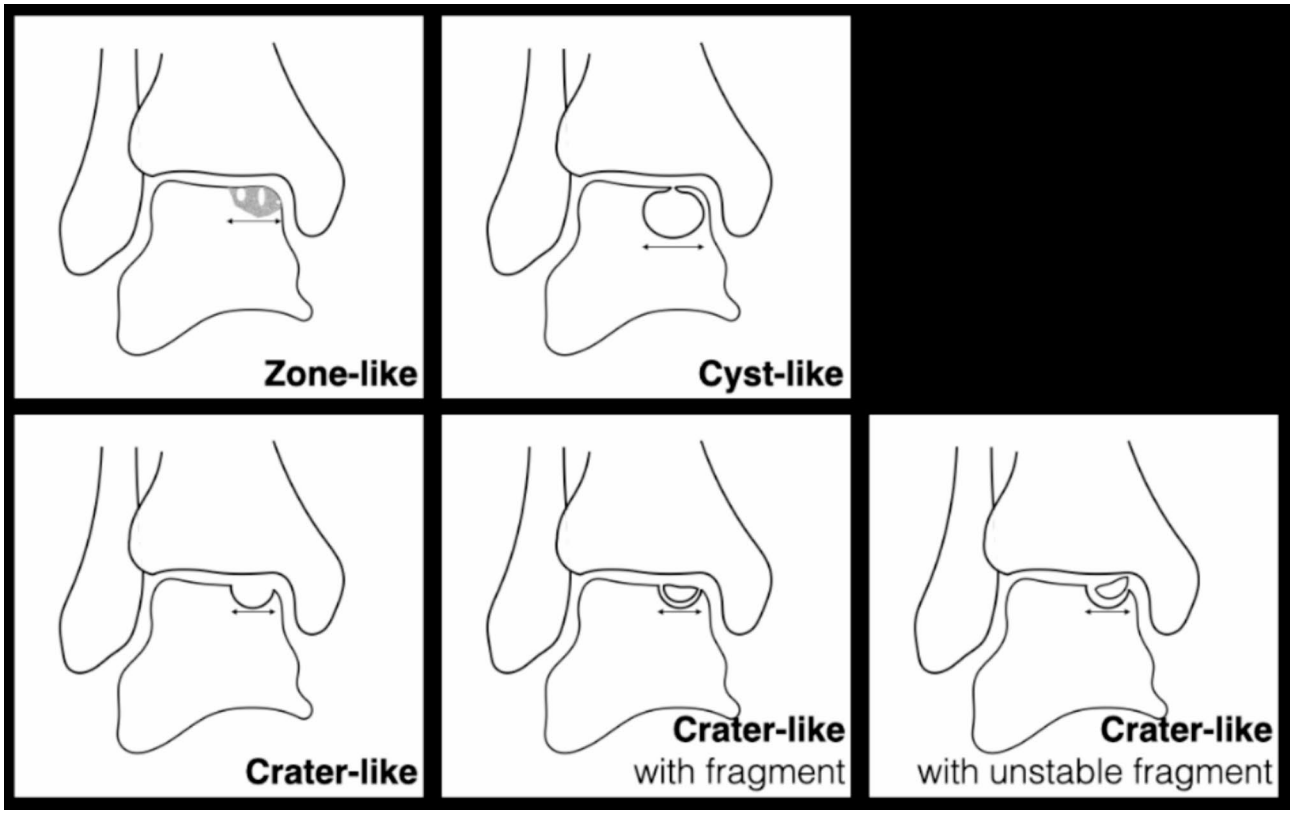

Fig. 2 Description of different morphological types of OLTs

0.79) and volume (4/3 π abc; 4/3 × 0.79 x AP x CC x ML).
- The extent of bone marrow edema (measured on MRI); classified as mild, moderate, severe.
- Signs of unstable fragments (measured on CT).

Sample size

The primary outcome of this study is the OxAFQ-C at one year follow-up. Based on the current literature, the upper boundary of the minimally important difference is used, which is 17% in the OxAFQ-C physical domain [14]. A sample size of 35 patients in each group is needed for an 80% study power using a standard deviation of 25. Level of significance was set at ≤0.05. Generally, a loss to follow-up of 5–10% is reported for orthopedic research [19]. To compensate for potential loss to follow up of 7.5%, a total of 38 patients will be included in both groups.

Data collection management

All data will be collected using the cloud based electronic data capture system Castor-EDC. All baseline characteristics and questionnaires will be stored in this data platform. Personalized data will be converted into a specific study number which is stored in a protected computer environment in order to anonymize patient related data. The study number is used in all data collection and study reports. All participating researchers will have access to the Castor platform, patient files and key numbers of the included patients.

Radiological measurements will be performed by experienced musculoskeletal radiologists. Outcomes of the radiological measurements will be stored in a protected excel file which is only accessible for participating researchers.

Data monitoring

Monitoring of the data will be performed by the coordinating researcher according to the schedule described in Table 2. The coordinating investigator will submit a summary of the progress of the study to the accredited Medical Ethical Test Committee (METC) once a year, which is per protocol. Information will be provided on the date of inclusion of the first subject, numbers of subjects included and numbers of subjects that have completed the study, serious adverse reactions, other problems, and amendments. Safety monitoring is not required as this study is considered as ''low-risk''.

Subjects can leave the study at any time for any reason if they wish to do so, without any consequences. The investigator can decide to withdraw a subject from the study for urgent medical reasons. Another reason for

withdrawal can be an unsatisfactory result of one of the non-operative strategies which results I surgical intervention, based on a shared decision-making process between the surgeon, patient and caretakers.

Statistical analysis

Baseline characteristics will be presented with descriptive statistics. In case of normality of the data, results will be presented with a mean and standard deviation. In case of non-normality of the data, results will be presented with median and range. All statistical analyses will be performed with R statistical software (version 4.1.2, 2021,Foundation For Statistical Computing, Vienna, Austria) [20].

Primary outcome

An unpaired t-test will be used for the comparison between the OxAFQ-C group means in case of numerical data at the mentioned times of follow up. In case of non-normally distributed data, the non-parametric Mann-Whitney U test will be conducted to compare both groups. In both cases, a p-value less than 0.05 will be considered significant. Patients will be analyzed according to the intention to treat principle, which indicates that patients will be analyzed in their group of origin regardless of what kind of treatment was received later during the study period.

Secondary outcomes

Radiological healing of the osteochondral lesion will be analyzed in a descriptive way. CT scans will be used to assess change in lesion size. For each lesion, the anterior-posterior diameter (mm), medial-lateral diameter (mm) and cranial-caudal diameter (mm) will be calculated. Surface will be calculated with the following formula: 0.79 x AP x ML. Volume will be calculated according to the ellipsoid formula [21]. MRIs will be used to assess the amount of bone marrow edema.

All size measurements will be conducted by two independent researchers. To assess inter- and intra-observation reliability an Inter Class Correlation (ICC) will be calculated afterward. A two-way random ICC will be calculated to assess the inter-observer reliability and a two-way mixed ICC will be calculated to assess the intra-observer reliability. For the parameters volume and surface, a mean size will be calculated on each moment of follow-up. A repeated measures ANOVA will be used to test for significance of change in these parameters. Additionally, on the long term, another secondary outcome will be the conversion to surgery rate. This conversion to surgery rate over time will be expressed in a Kaplan-Meier curve.

For other secondary outcomes, an unpaired t-test will be used for the comparison between the group means in case of numerical data. In case of ordinal data, the non-parametric Mann-Whitney U test will be conducted to compare both groups. In both cases, a p-value less than 0.05 will be considered significant.

Dissemination

We aim to present the results of this study in PubMed indexed journals. With these articles, we aim to contribute to an evidence-based protocol for OLTs in the pediatric population. Additionally, we aim to present results of this study on (inter)national conferences.

Discussion

This protocol reports on the study design of the CARE study. This protocol aims to setup a study for evaluating different types of non-operative management in pediatric patients suffering from an OLT. As the first treatment in line is always non-operative, it is important to treat patients with the most appropriate non-operative management. Non-operative management aims to heal the OLT before more rigorous (surgical) strategies are initiated. In the current literature, all studies concerning non-operative management for pediatric OLTs are retrospective and none of them reports on the radiological course of OLTs. Additionally, the total number of all included patients in non-operative management in the current literature is 200. Few studies reporting on immobilization and the ‘‘skillful” neglect strategy [7]. However, no comparison is made between both type of treatments. As such, our current prospective comparative cohort study differs from the current literature as it will compare both non-operative strategies in a prospective manner.

In our intervention group, patients will have immobilization and supervised rehabilitation. This treatment strategy is frequently reported in the current literature where it was successful in approximately 4 out of 10 patients [7]. Additionally, it has shown its healing potential for osteochondral lesions in the knee joint and therefore, it can be implicated that immobilization and supervised rehabilitation may facilitate healing of the OLT. However, despite this assumption, it was never proven in the current literature for OLTs. The disadvantage of this intervention is that patients are restricted in their movement which can cause a decrease in quality of life. If casting and supervised rehabilitation do not lead to improved outcomes comparing to the ‘‘skillful” neglect, patients would be mistakenly restricted in their movement. Despite the potential effective treatment with casting and supervised rehabilitation, this strategy is never compared to the ‘‘skillful” neglect strategy.

The CARE study will compare immobilization and supervised rehabilitation with the ‘‘skillful” neglect strategy. Patients in the intervention group will have immobilization with 4 weeks of normal casting and 4 weeks of

immobilization with a removable cast and weightbearing boot. Subsequently, they will have supervised rehabilitation. This strategy will be compared in terms of clinical- and radiological outcomes with the patient group who will have a ''skillful" neglect treatment in which patients adjust their activities within the boundaries of pain.

This study has been designed to compare clinical- and radiological outcomes between two different non-operative strategies for treating OLTs in the skeletally immature population. We hypothesize that a period of immobilization and supervised rehabilitation will lead to better clinical- and radiological outcomes compared to the ''skillful" neglect treatment. Based on the results of this study, an evidence-based treatment protocol for non-operative management for pediatric OLTs can be provided.

To the best of our knowledge, this is the first multicenter prospective comparative cohort study to assess patient reported outcomes and radiological outcomes after different types of non-operative treatment for OLTs.

Abbreviations

OLT	Osteochondral lesions of the talus
JIA	Juvenile idiopathic arthritis
OxAFQ-C	Oxford ankle and foot questionnaire for children
PedsQL	Pediatrics quality of life
EQ-5D-y	EuroQol-5 dimension youth
MREC	Medical research ethical committee

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Author contributions
PS drafted the study idea. TB, CvB and PA secured funding for this study. All authors were involved in the study design. TB, JS and JD will be responsible for the clinical follow up under direct supervision of PS, GK and CvB. FS, RH and MT will be responsible for the radiological follow-up under supervision of MM. All authors contributed to this manuscript and approved the final version.

Data availability
No datasets were generated or analysed during the current study.

Declarations

Ethics approval and consent to participate
The study was approved by the local Medical Ethics Committee of the Amsterdam University Medical Centre with reference number METC NL78874.018.22and was performed in accordance with the principles of the Declaration of Helsinki and the medical Research Involving Human Subjects Act (WMO). In case of protocol amendments, the METC of the Amsterdam University Medical Centers will directly be informed.

Consent for publication
Not applicable.

Competing interests
The authors declare no competing interests.

Author details
[1]Department of Orthopedic Surgery and Sports Medicine, Amsterdam UMC, Location AMC, University of Amsterdam, Meibergdreef 9, Amsterdam 1105 AZ, the Netherlands
[2]Academic Center for Evidence based Sports medicine (ACES), Amsterdam UMC, Meibergdreef 9, Amsterdam 1105 AZ, the Netherlands
[3]Amsterdam Collaboration for Health and Safety in Sports (ACHSS), International Olympic Committee (IOC) Research Center, Amsterdam UMC, Meibergdreef 9, Amsterdam 1105 AZ, the Netherlands
[4]Department of Orthopedic Surgery, Amphia Hospital Breda, Molengracht 21, Breda 4818 CK, The Netherlands
[5]Departement of Orthopedic Surgery, Erasmus Medical Center – Sophia Children's Hospital, Dr. Molewaterplein 40, Rotterdam 3015 GD, The Netherlands
[6]Department of Radiology and Nuclear Medicine, Amsterdam UMC, Location AMC, University of Amsterdam, Amsterdam, The Netherlands
[7]Department of Radiology and Nuclear Medicine, Amphia Hospital Breda, Molengracht 21, Breda 4818 CK, The Netherlands

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