CAsting and REhabilitation for osteochondral lesions of the talus in the skeletally immature: a prospective comparative observational study

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Ethical review	Approved WMO
Status	Pending
Health condition type	Tendon, ligament and cartilage disorders
Study type	Interventional

Summary

ID

NL-OMON54282

Source
ToetsingOnline

Brief title
CARE study

Condition

- Tendon, ligament and cartilage disorders

Synonym
cartilage defect, Osteochondral defect

Research involving
Human

Sponsors and support

Primary sponsor: Orthopedie

Source(s) of monetary or material Support: Ministerie van OC&W,European Pediatric Orthopaedic Society (EPOS)

Intervention

Keyword: Casting, Osteochondral, Rehabilitation, Skeletally Immature

Outcome measures

Primary outcome

The primary study outcomes consist of the Oxford Ankle Foot Questionnaire for

Children, Nummeric Rating Scale, Pediatric Quality of Life Inventory,

and the Child Vulnerability Scale.

Secondary outcome

The secondary outcome of this study is the detection of radiologic changes of

the osteochondral lesion during the follow up.

Study description

Background summary

An osteochondral lesion (OCL) is a lesion of the articular cartilage and underlying subchondral bone. There is a hypothesis that OCLs in the pediatric population are congenital and may be diagnosed by accident after trauma. Additionally, OCLs can occur after trauma or in patients with juvenile idiopathic arthritis (JIA). Patients experience pain during weightbearing which can cause a significant impact on the health status of patients. Conservative management is frequently focused on supervised neglect till skeletally maturity has been reached. This means that patients are advised to alter their physical activities during their growing period. Previous research on OCLs in the knee of skeletally immature patients has shown improved radiological and clinical outcomes after a supervised immobilization- and rehabilitation protocol. However, as of yet, no studies describe the role of a standardized immobilization and supervised rehabilitation protocol in the conservative management of OCLs of the ankle in the skeletally immature population. For that reason, a comparative study is needed in order to investigate if immobilisation and supervised rehabilitation is superior to the

current conservative strategy.

Study objective

The aim of this study is to improve the conservative management of OCLs of the talus in the skeletally immature due to the comparison of two different conservative strategies. An optimal conservative treatment can result in a better quality of life and help to avoid surgical management when patients are skeletally mature.

Study design

Potential candidate and their parents/caretakers will be provided with information about the study. If patients confirmed their participation, they will be assigned to the intervention or control group based on personal preference. Patients in both groups will be followed up with questionnaires concerning ankle function, ankle pain and returning to sport. Questionnaires will be taken at the following moments: baseline, 16 weeks, 26 weeks, 52 weeks, 104 weeks. X-rays, CT-scans and MRI's will be conducted at baseline. Subsequently, MRI's and X-rays will be conducted at 52 weeks and 104 weeks.

Intervention

Patients in the intervention group will undergo non-weightbearing immobilization with a cast for 8 weeks in phase one. 4 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. In phase 2, a supervised rehabilitation will be performed till week 16 after which phase 3 will start at week 16-18 In phase 3, patients will resume running, jumping and acyclic sporting activities under supervision of a physical therapist.

Study burden and risks

The extra burden that participants of this study will have is completing the questionnaires at the above mentioned moments. The completion of all questionnaires at each follow-up moment will take approximately 30 minutes. Subsequently, patients will have radiologic follow-up at baseline, 16 weeks, 1 year, 2 years, 5 years and 10 years. Only the radiologic follow-up at 16 weeks, 5 years and 10 years is an extra burden in context of this study.
Participation in this study does not involve any risks.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)

Inclusion criteria

Symptomatic, stable osteochondral lesion of the talus
Diagnosed on a Computed Tomography (CT) scan
Open physes of the distal tibia confirmed by a specialized musculoskeletal or pediatric radiologist

Exclusion criteria

Acute lesions
Instable lesions
Surgical treated OLTs

Systemic diseases that can influence cartilage conditions such as hemophilia

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-05-2024
Enrollment:	76
Type:	Anticipated

Ethics review

Approved WMO Date:	19-05-2023
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	15-04-2024
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL78874.018.23