PLEASE NOTE: *This trial has been registered retrospectively.*

Trial Description

Title

Prospective randomized study on immobilization of upper extremity fractures using wood and plastic casts in children and adolescents under 16 years of age

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

Non displaced upper extremity fractures and dislocations in children and adolescence are treated by stabilizing and immobilizing casts. However, the classical and traditional material for the immobilization and redression of the fractures represents a plaster of Paris. The advantages of the plaster of Paris include exact modeling properites and its high stability. The disadvantages include skin macerations, the risk to develop a compartment syndrome, heavy weight and time-consuming cast procedure.
Over the past two decades, synthetic (fiberglass or synthetic resin) casts have become popular. However, an additional or further correction of a cast is not possible as with white plaster. Advantages of synthetic cast materials include good modeling properties, high stability, low weight and fluid resistance. Disadvantages include the short processing time, the need to wear a protective clothing (gloves, apron), the accidental separation of the layers of mechanically stressed areas, and disposal as hazardous waste.
Furthermore, synthetic casts and plaster of Paris are not sustainable materials (negative ecological balance).

The Woodcast® from the Finnish company Onbone Oy is a heat-deformable (thermoplastic) cast material made of wood and biodegradable composite (wood-polymer composite material). With the same stability and X-ray negativity compared to synthetic casting materials, the manufacturer promises the following advantages:

- More efficient, biodegradable material
- No outgassing of chemicals
- Possibility of removing the Woodcast® dressings without usage of oscillating saw
- Possibility of recycling of removed cast pieces
- Postformability after hardening by repeated heating

Woodcast® has been studied in 4 Finnish studies as well as under experimental laboratory conditions. However, only one study is available on PubMed. Pirhohnen et al. performed mechanical stress tests on immobilized joints of adults and

cylindrical cast samples in 2013. The authors showed that the Woodcast® has the same stability and rigidity as the usual cast made of plaster of Paris and synthetic materials. Lindfors et al. reported in 2012 and 2014 in a prospective study on adults the sustainability of the Woodcast® material, the user-friendly application, the excellent X-ray transparency and the good mechanical stability of the product. However, the control group was not included in this study.
Hirsimäki et al. compared the reliability of Woodcast® material in 2014 with rigid and semi-rigid casts to immobilize the ankle and foot. The authors demonstrated the full strength of the foot while reliably immobilizing the ankle through semi-open splints without circulation. In all previously published studies, Woodcast® was evaluated only in adults. Studies in children and adolescence are missing.

The aim of this study is therefore to compare two different casting materials with regard to biomechanical-physical parameters (strength, resistance, real deformability) and clinical outcomes (patient satisfaction, wearing comfort, advantages and disadvantages during dressing and reduction ect.). With the gained knowledge and in the case of the superiority of the wood cast material compared to the synthetic cast, the improved environmental sustainability, recycling of the material as well as improved comfort for the pediatric patients can be achieved.

Brief Summary in Scientific Language

Two modern casting materials (Woodcast® vs. Dynacast®) should be company-independent tested for their suitability regarding to biomechanical properties and their clinical applicability. The following parameters should be examined:
- Stiffness of the cast material
- Patient acceptance
- User-friendliness for the medical staff

In the first part of this study, a standardized questionnaire will be used to investigate the clinical outcomes between two investigated cast materials during cast application, wearing, and removing.
In addition, in the second part of the study, cast materials should be analyzed at the HTWK (University of Applied Sciences Leipzig) for biomechanical and chemical properties.

Stratified (2 genders x 3 age groups) randomization should be used including a total of 6 strata:
• Strata no. 1 = male, 0 - 6 years
• Strata no. 2 = male, 7 - 12 years
• Strata no. 3 = male, 13 - 16 years
• Strata no. 4 = female, 0 - 6 years
• Strata no. 5 = female, 7 - 12 years
• Strata l no. 6 = female, 13 - 16 years

The randomization sheets is protecting by using standard envelopes with windows. Furthermore, the randomization sheets contain a framed field with indication of the study arm, either "Woodcast" or "Synthetic cast" and the 4-digit patient number. The patient number is created by the stack-number and the consecutive number.

Definition complications:

Material-related complications
- Material breakage
- Pressure mark

Fracture-related complications
- Unscheduled Follow-up
- Pain (assessed by numeric rating scale (NRS))
- Secondary dislocation
- Change of procedure

Parents, children and medical staff are interviewed using the standardized questionnaire. The questionnaire should be completed in two steps. First, the questions concerning the cast material should be answered by the children / parents as well as by the medical staff. The completion of the questionnaire takes place at the last follow-up by removing the cast.

In both groups, clinical and radiographic follow-up procedures are performed by the physicians familiar with the study as follows. The X-ray examinations in both groups are part of the routine examination of the included fractures and not study-specific.

Day 0: Cast applications
Day 1: Examination of the cast, motor function, vascularization and sensitivity by physician
Day 5: Examination of the cast, motor function, vascularization and sensitivity by physician and X-ray examination
Day 10: Examination of the cast, motor function, vascularization and sensitivity by physician and X-ray examination
Day 14: Examination of the cast, motor function, vascularization and sensitivity by physician
Day 21: Examination of the cast, motor function, vascularization and sensitivity by physician and X-Ray examination* as well as completion of the treatment

At each planned follow-up, a standardized physical examination should be performed and the current anamnesis obstained.

In the case group (Woodcast) and in the control group (Dynacast), children (age ≤ 16 years) with following injuries as well as primary conservative therapy and without operative treatment should be included:

Forearm fractures (epiphysealysis, metaphyseal and diaphyseal fractures)
Supracondylar fractures (Type type I – Iia after Laer)
Epicondylar fractures
Condylar fractures with conservative therapy
Duration of immobilization ≥ 2 weeks

Adults or children (age> 16 years) with the following injuries are not included in the study:
Fractures requiring reduction or surgical treatment
Acute elbow dislocations
Pregnancy

Do you plan to share individual participant data with other researchers?

Yes

Description IPD sharing plan

Data sharing on reasonable request

Organizational Data

- DRKS-ID: **DRKS00017440**
- Date of Registration in DRKS: **2019/06/13**
- Date of Registration in Partner Registry or other Primary Registry: **[---]***
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **379/17- ek , Ethikkommission an der Medizinischen Fakultät der Universität Leipzig**

Secondary IDs

Health condition or Problem studied

- ICD10: **S50-S59 - Injuries to the elbow and forearm**
- ICD10: **S40-S49 - Injuries to the shoulder and upper arm**

Interventions/Observational Groups

- Arm 1: **Woodcast® arm**
- Arm 2: **Dynacast® arm**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Active control (effective treament of control group)**
- Purpose: **Treatment**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

Stress stability of the cast material. Stress stability is defined as absence of any deformations or fractures within the cast during study period (within 21 or 28 days after the cast application). Non-used casts materials shoul be additionally biomechanically and chemically tested at the HTWK.

Secondary Outcome

Subjective evaluation of the patient / medical staff for the survery of patient acceptance and ease of use for the medical staff determined by specific questionnaires.

Operationalization of the secondary endpoint:

Clinical applicability
• Application time (mean and standard deviation)
• Investigation after the learning curve with n = 20 patients per cast material
• Application comfort (patient and staff) and complications
• Dwell period, comfort and complications
• Comfort by cast removal and complications
• Chemical test
• Complications

The time of the secondary endpoint measurement is the entire study period (21 or 28 days after the cast application).

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- Medical Center **Klinik und Poliklinik für Kinderchirurgie, Leipzig**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2018/03/01**
- Target Sample Size: **150**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **0 Years**
- Maximum Age: **16 Years**

Additional Inclusion Criteria

Children areeligible when they are under 16 years of age and presented with an acute, symptomatic, low-risk fractures of the upper extremity within 48 hours after injury. The fractures included non-displaced forearm fractures (distal radial epiphysiolysis, medtaphysical and diaphysical fractures), supracondylar fractures of the humerus (type I and type IIa fractures), epiconylar and condylar humeral fractures with immobilization time of at least two weeks.

Exclusion criteria

Adults or children (age> 16 years) with the following injuries or conditions should be excluded from the study:
Fractures requiring reduction and / or surgical treatment
Acute elbow dislocations
Pregnancy

Addresses

- **Primary Sponsor**

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Sources of Monetary or Material Support

- **Institutional budget, no external funding (budget of sponsor/PI)**

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Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2019/11/30**

Trial Publications, Results and other documents

** This entry means the parameter is not applicable or has not been set.*
**** This entry means that data is not displayed due to insufficient data privacy clearing.*