Foam splint versus spica cast - Early mobilization after hip reconstructive surgery in children - A prospective randomized clinical trial

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Study protocol

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Abstract

Background Surgical hip joint reconstruction is the method of choice for children and adolescents with developmental dysplasia of the hip (DDH). After surgery, immobilization using a spica cast is considered to be the gold standard for preventing redislocation of the hip, dehiscence of the tightened hip joint capsule or secondary dislocation of the osteotomy. Neverthess, spica cast treatment may cause complications like hygiene problems, skin lesions, neurological deficits and rigidity of the adjacent joints. An alternative for postoperative immobilization is a foam splint. The purpose of this randomized controlled trial is to compare spica cast and foam splint immobilization after hip reconstruction in children and adolescents with DDH. The hypothesis of this study is, that foam splint immobilization leads to a higher satisfaction during postoperative aftercare in the patients and their caretakers. A further intent of the study is to analyse the complications occurring under the immobilization.

Methods In a prospective randomized clinical trial children and adolescents (age: 4-14 years), who were diagnosed with DDH and received hip reconstruction surgery were included. Patient recruitment, group allocation, surgery and aftercare will be carried out at the Department for Department for Orthopedics and Traumatology, Kepler University Hospital, Linz, Austria. The approval of this study was granted by the local ethics committee (EK1183/2018) and a written informed consent will be obtained from each patient or his legal representative before start of the study. The study is funded by the Medical Society of Upper Austria and registered in the German Clinical Trials Register (DRKS-ID: DRKS00016861). A standardized questionnaire (SF-36, EQ-5D, CPCHILD) as well as a radiological assessment is gathered before, six and twelve weeks after surgery. Statistical methods are epidemiological calculations, analysis of covariance, t-test, chi-square test and graphical methods for visualisation. Power analysis showed a minimum optimum sample size of 15 individuals per group (t-test, two-sided, Cohen d 1.1, alpha=0.05, 1-beta=0.80).

Discussion Recent retrospective studies suggest that foam splint immobilization after hip reconstruction surgery is a safe and feasible method, promising fewe complications rates compared to spica casting. Nevertheless, no prospective randomized clinical trials have been published to prove the promised and suspected benefits of foam splints compared to spica cast immobilization. Clinical trials on children, especially with physical and mental disorders, need to be planned with rigorous care for general ethics and legal rights. Advice from ethical review committees, self-help groups and legal advisers is mandatory. The presented clinical trial was planned under such strict standards and meets ethical and legal criteria. The results of this clinical trial will be published in national and international meetings for pediatric orthopaedics as well as in international journals for pediatric orthopaedics. The aim is to provide profound criteria for the usage of a foam splint instead of casting in immobilization after hip reconstructive surgery. Benefits for the patients may be fewer complications and no need for a second anaesthesia for recasting. Up to now, a comparable study does not exist.

Background

Developmental dysplasia of the hip joint (DDH) and deformations of the proximal femur may be congenital. In addition to that many patients with neuromuscular disorders like cerebral palsy (CP) or myelomeningocele (MMC) have neuromuscular dysplasia of the hip (NDH) and/or dislocation of the hip. (1) Results may be pain when walking/standing/sitting as well as problems with walking or even the disability to stand.

In early childhood DDH or dislocation of the hip may be treated by casting or splinting. In case of failed conservative treatment surgical reposition and reconstruction of the hip is needed. Children with neuromuscular disorders show a high incidence of hip dislocations and failed conservative treatment due to NDH and DDH.(2) In CP, different authors could show an incidence of hip dislocation in 18–60% of their patients.(3) Especially in older children, who are already able to walk, tight soft tissue makes the procedure challenging. In most cases, a combination of soft tissue and bony procedures is necessary to achieve a reduction of the joint.(4, 5) After surgery immobilization usually is done by spica-casting for six weeks, followed by physiotherapy.(6) Most surgeons prefer casting in order to avoid secondary dislocation especially in patients with spastictity. Possible complications are well-known: hygienic problems, skin lesions, neurological complications, rigidity of the joints after casting. In common, a change of the spica-cast is performed in a second short general anaesthesia two weeks after surgery. An alternative for postoperative immobilization is a foam splint. On one hand it protects the surgically treated hip from dislocation, on the other hand it is possible to access the wound easily and provide physiotherapy to the adjacent joints.

Retrospective studies showed the safety of the foam splint concerning the healing of the bone and promised fewer complications. Gather et al. showed in 2018, that foam splinting is not inferior to spica casting concerning major complications such as dislocation of the bone wedge, avascular necrosis of the acetabulum or femur, lack of non-union, or nerve injury.(7) Despite retrospective data, there is no consensus about the way of post-operative immobilization in the treatment of DDH.

In a prospective randomized clinical trial we now want to show, that the foam splint leads to a higher satisfaction with the postoperative situation in the patients and their caretakers. Furthermore we want to show a lower number of complications, than in our control-group. Benefits for the patients may be fewer complications, a higher quality of life during the aftercare process and no need for a second anaesthesia for recasting. Up to now, a comparable study does not exist to our knowledge.

Methods/design

We designed a non blinded, prospective randomized clinical trial to prove our theory. Ethical approvement was obtained, a scientific grant by the Medical Society of Upper Austria funds our research. The clinical trial is registered at the German Clinical Trials Register (DRKS-ID: DRKS00016861).

The main issue is: Does foam splinting lead to a higher satisfaction of the patient and a higher quality of care?

The side issue is: Are there any further advantages in the use of foam splinting. Is foam splinting cost-effective? Are there fewer complications such as hygienic problems, skin lesions and neurological complications?

The hypothesis to prove is: Foam splinting for immobilization after hip reconstructive surgery leads to a higher satisfaction of the patients and a higher quality of care than spica casting, measured with the parameter CPCHILD (Caregiver Priorities and Child Health Index of Life with Disabilities).(8)

The clinical endpoint is the completion of postoperative immobilization, usually six weeks after surgery.

The location for recruitment is the Department for Orthopedic and Trauma Surgery, the Kepler University Hospital, Linz, Austria.

Patients to include are children and adolescents from 4 to 14 years of age with the diagnosis dysplasia of the hip with indication for hip reconstructive surgery. Methods of surgery included are acetabular osteotomy following the technique of Salter, Pemberton, Dega and derotation/varisation osteotomy of the proximal femur. Included indications for surgery are Reimers migration index 40% or higher or 25-40% with progression, Tönnis classification II or higher or AC-Index above the Tönnis-standard. The completion of the standardized questionnaire before surgery, after 6 and 12 weeks and partizipation in the radiological assessment 6 and 12 weeks after surgery are required for inclusion. Post-trial care is performed within a standardized yearly routine check-up.

An obtained informed consent of the patient and legal guardian is mandatory and will be collected by the surgeon.

The calculation of sample size used a two-sided t-test, effect of Cohen d 1.1, alpha=0.05, 1-beta=0.80 and resulted in a number of 15 patients per group.(9)

Assignment process is random, using a coin-toss.

Criteria for exclusion are a lack of consent and cooperation.

Criteria for termination of the study is discontinuation of usage of foam splinting due to adverse events.

Individual criteria for termination of the study are loosening of osseous correction and withdrawal of informed consent.

Data storage and analysis is done pseudonymised. No data will be given to external partners, therefor no additional data monitoring committee is needed. No auditing is planned.

Statistical methods include a detailed epidemiological description with mean standard-deviation, minimum, maximum, median at continuous data and scores, relative frequency for explained variables. The main target, the CPCHILD-score, is analyzed using analysis of covariance using the assigned group

as factor and the baseline score as discrete variate. All other characteristics are analyzed with a t-test or chi-square-test. When appropriate, graphical methods for visualisation are used.

The algorithm of the recruitment process is shown in figure 6. Patients are recruited in the outpatient clinic for pediatric orthopedics and neuro-orthopedics at the Kepler University Hospital, Linz, Austria. The planning and the surgical procedure itself are performed at the Kepler University Hospital Linz, Department for Orthopedics and Traumatology. All planned postoperative follow-up checks are done at the outpatient clinic for pediatric orthopedics and nero-orthopedics at the Kepler University Hospital.

None of the planned check-ups differs from our clinical standards, no additional appointment is necessary. The postoperative x-rays after 6 and 12 weeks are according to our clinical standard. Furthermore, no radiological or invasive diagnostic or therapeutic method is used.

Included patients are children from 4 to 14 years of age, needing hip reconstructive surgery followed by immobilization according to our criteria for inclusion to the study. Following the inclusion, a coin-toss randomization is performed.

Group one is treated with a spica cast in slight flexion of the hip of about 10-15 degrees, 10 degrees inward rotation of the hip and 30 degrees of abduction of the hip. (Figures 2 and 3) Two weeks after surgery, a second short general anaesthesia for removal of the skin suture and changing the cast is necessary.

Group two is treated using immobilization with a foam splint for six weeks in slight flexion of the hip of about 10-15 degrees, 10 degrees inward rotation of the hip and 30 degrees of abduction of the hip. (Figures 4 and 5) No second anaesthesia is needed in group two. During the period of immobilization in group two, physiotherapy of the lower extremity is performed considering the patient's needs.

There is no difference in the surgical technique between both groups. Standardized questionnaires are used to measure the quality of life and the quality of aftertreatment 6 and 12 weeks after surgery. The questionnaires used are the CPCHILD (8) the SF-36 (Short Form 36) (10) and the EQ-5D (Euro Quality of Life 5D) (11). Mobility pre- and postoperatively is measured using the GMFCS-scale (Gross Motorfunction Classification System). Pre- and postoperative geometry of the acetabulum is evaluated at each follow-up using the AC-angle (Acetabular angle), CE-angle (Center-Edge-angle) and the migration index according to Reimers. Complications are counted and cost-effectiveness is calculated.

[Figure 1]

Patient and Public involvement

The planning study was supported by the local ethical review committee including the representative for disabled patients, which provides professional ethical and legal advice. The ethical review committee reviewed the study protocol during the planning of the clinical trial and gave advice on ethical and legal

topics. The committee partnered with us for the design of the study, the informational material to support the intervention, and the burden of the intervention from the patient's perspective.

Pseudonymisation of obtained data is performed. Data will be published after data collection in oral and written communication. Patients are informed of the results during their routine check-ups.

Discussion

Minors are not legally able to give informed consent and need their legal guardian's consent. The decision to participate in a clinical trial needs to be made carefully, with in depth discussion with the legal guardian, and appropriate discussion with the child, depending on their age and capacity. Dysplasia of the hip needs to be treated before the child is old enough to give informed consent, to prevent deterioration or even loss of gait and posture. There is evidence that hip reconstructive surgery has a positive effect on the quality of life of children with cerebral palsy.

Di Fazio et al showed the positive effect of hip reconstructive surgery on quality of life in children with cerebral palsy in 2016. (8)

Despite the long history of surgical correction of the hip and pelvis, there is no consensus about the duration of post-operative immobilization in the treatment of developmental dysplasia of the hip. (6)

In 2018 Murgai et al described a safe technique of foam padding in postoperative lower extremity casting (12).

Gather et al. showed the safety of immobilization using a the foam splint after surgical reconstruction of pelvic and hip in patients with DDH. (7) Nevertheless, these reports are retrospective case series.

Willing to improve evidence in postoperative treatment, this is the first prospective randomized clinical trial comparing the spica casts and foam splints for postoperative immobilization in patients with DDH, who receive hip reconstructive surgery. The purpose of this study is to evaluate quality of life and complication rates between these two different immobilization devices. The hypothesis is that foam splints lead to a higher quality of life during the period of immobilization, fewer complications and no need for a second anaesthesia for recasting. The aim is to provide profound criteria for the usage of a foam splint instead of casting in immobilization after hip reconstructive surgery.

The results of this clinical trial will be published in national and international meetings for pediatric orthopaedics as well as in international journals for pediatric orthopaedics. Informed consent for publication is obtained from each participant and legal guardian.

Strenghts and Limitations

Providing the first prospective randomized clinical trial on the topic of foam splinting and casting in immobilization after hip reconstructive surgery, the obtained data may support the decision-making in

postoperative care concerning safety and satisfaction of patients and caretakers. This clinical trial was planned under high ethical and legal standards and has passed the ethical review committees. Due to the high relevance of this topic for young patients with physical and mental disorders and because of the valuable study protocol, the trial is funded by the Medical Society of Upperaustria. The main limitation to achieve statistical significance may be the small number of participants of 15 patients in each group. Further studies may be needed to obtain reliable data.

Trial Status

Protocol Number 1.01, 11/19/2018. Trial started 5/2019, 4 of 30 planned subjects are included. Planned recruitment will be completed 12/2021

Abbreviations

CPCHILD Caregiver Priorities and Child Health Index of Life with Disabilities

CP Cerebral palsy

DDH Developmental dysplasia of the hip joint

EQ-5D Euro Quality of Life 5D

MMC Myelomeningocele

NDH Neuromuscular dysplasia of the hip

SF-36 Short Form 36

Declarations

Ethics approval and consent to participate

Ethical approvement was obtained

Ethics commitee: Ethikkommission des Landes Oberösterreich EK Nr: 1183/2018

All participants and their legal guardians must understand and subscribe the written informed consent form including the consent for publication, including potentially identifiable images

Consent for publication

All participants and their legal guardians must understand and subscribe the written informed consent form including the consent for publication, including potentially identifiable images

Availability of data and materials

The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request. Only authors have full access to the dataset.

Competing interests statement

Each author certifies that he or she, or a member of his or her immediate family, has no funding or commercial associations (eg. consultancies, stock ownership, equity interest, patent/licensing arrangements, etc) that might pose a conflict of interest in connection with the submitted article.

Funding

The trial is publicly funded by competitive grant by the Medical Society of Upperaustria, Dinghoferstraße 4, 4020 Linz, Austria; The funder has no role in collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication.

Authors' contributions

All authors contributed to the development of the study protocol, the statistical planning, the ethics committee proposal and the development of the manuscript; PL, JA, GG, MK, AH, TG developed the study protocol, TB developed the statistical section

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All authors agree with publication of this manuscript

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Figures

	STUDY PERIOD				
	Enrolment	Allocation	Post-allocation		Close-out
TIMEPOINT	$-t_1$	0	t_1	t_2	t_3
ENROLMENT:	X				
Eligibility screen	X				
Informed consent	X				
Allocation		X			
INTERVENTIONS:					
[Spica Cast]			♦——	——♦	
[Foam Splint]]			♦——	——♦	
ASSESSMENTS:		X	X	X	X
[CPCHILD]		X		X	X
[SF-36]		X		X	X
[EQ-5D]		X		X	X
[Complications screen]			X	X	X

Figure 1

the schedule of enrolment, interventions, and assessments. T1=surgery, t2=6 weeks after surgery, t3=12 weeks after surgery (SPRINT figure)

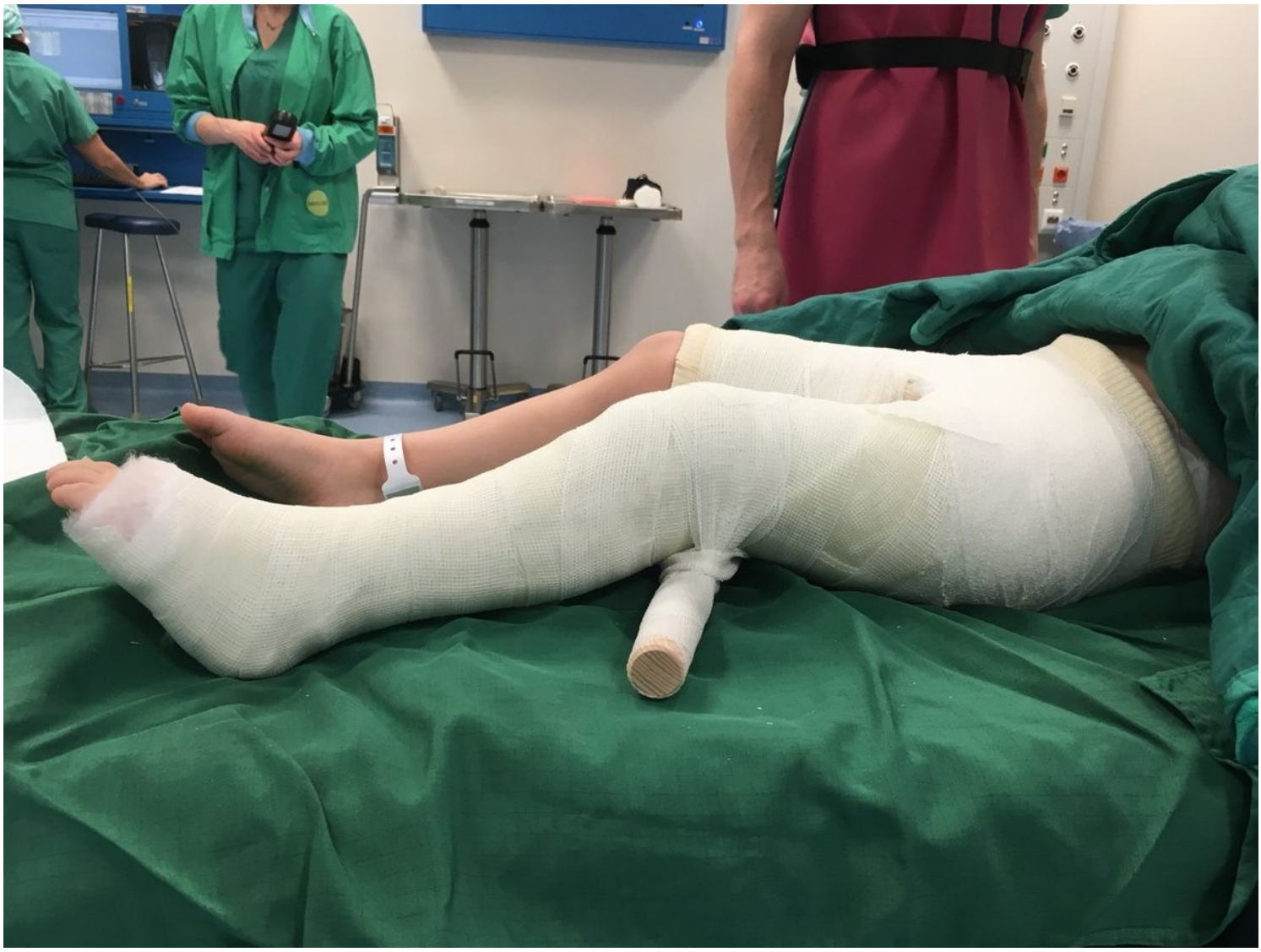

Figure 2

spica-cast

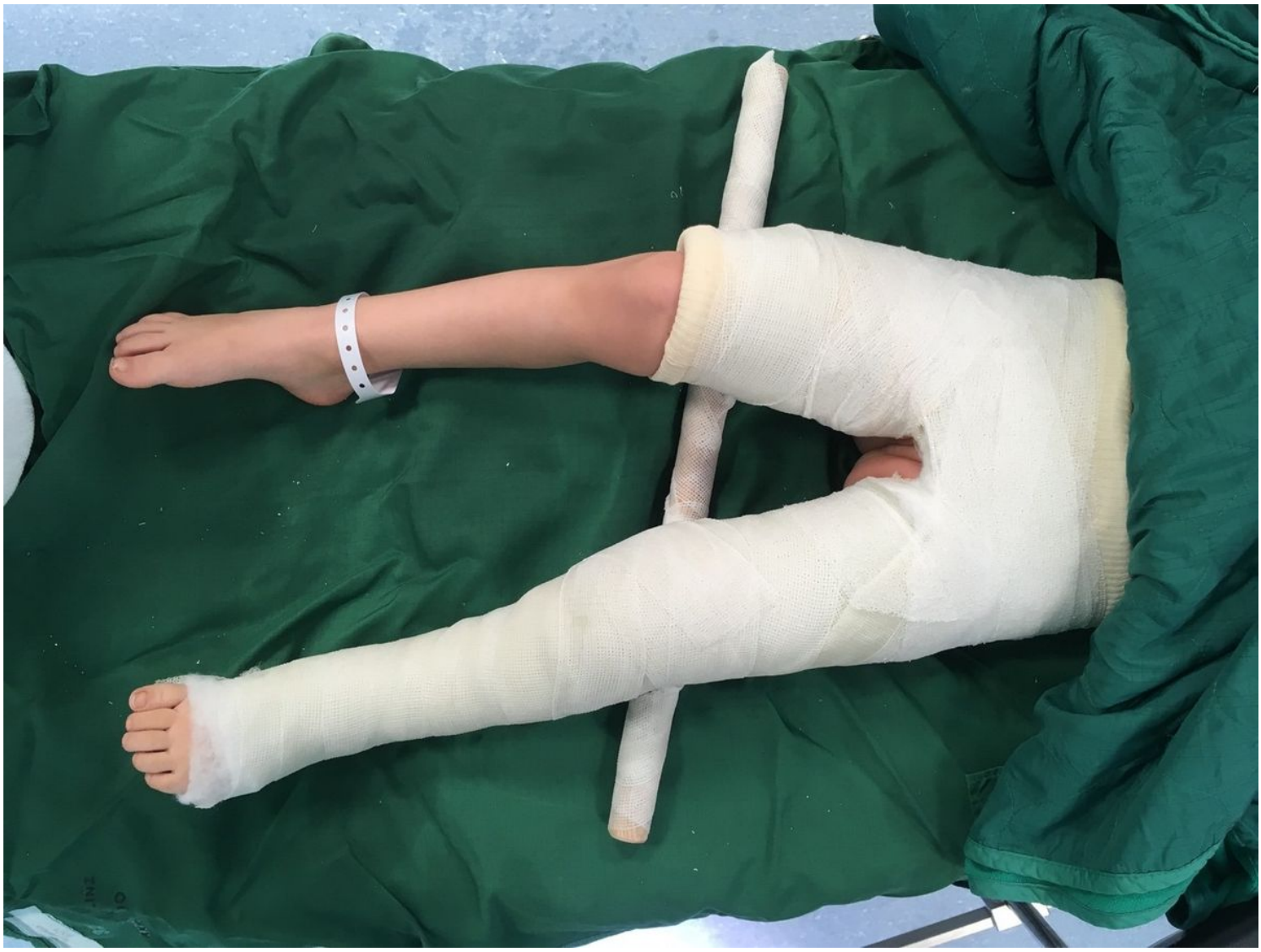

Figure 3

spica-cast

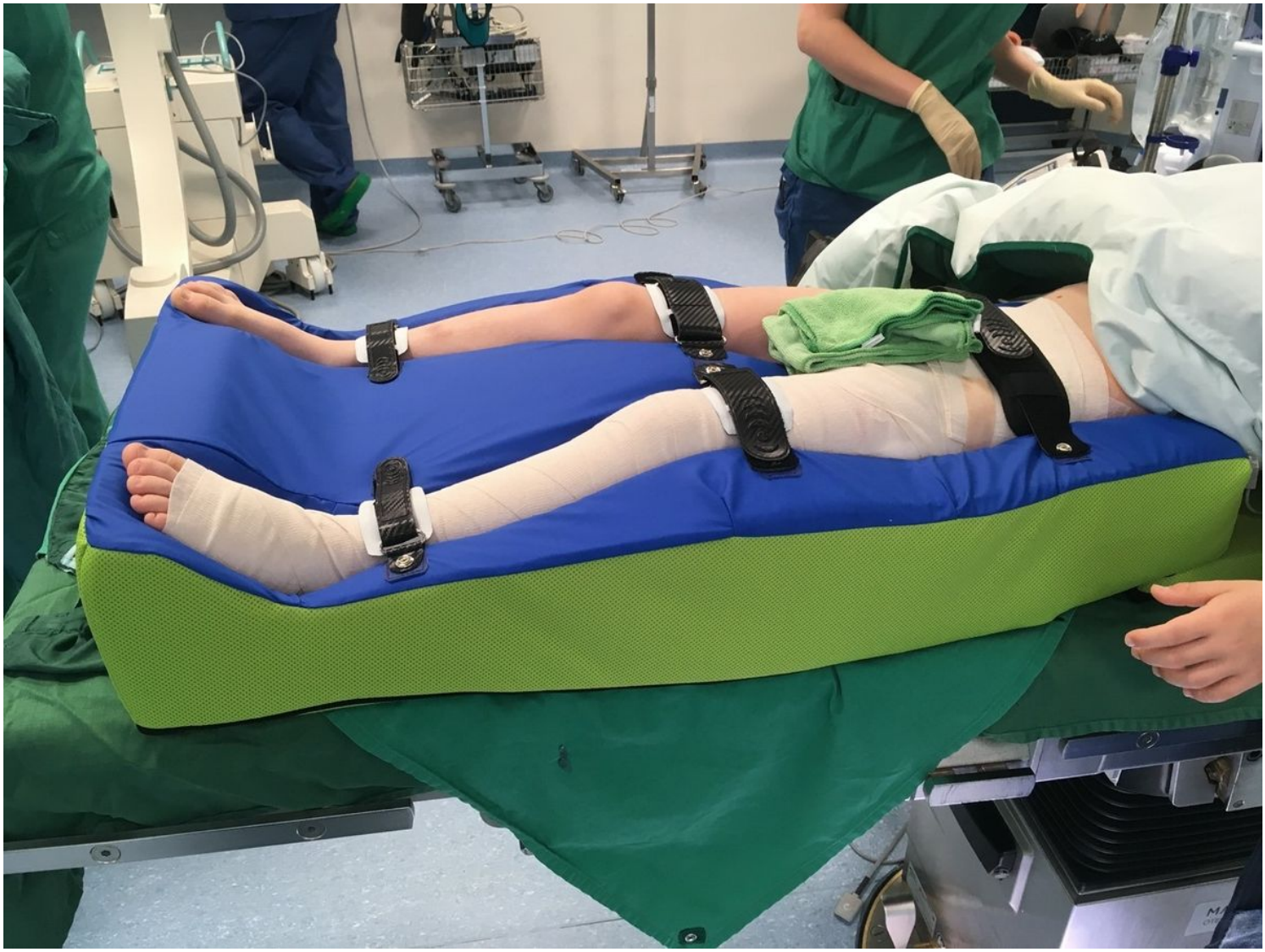

Figure 4

foam splint

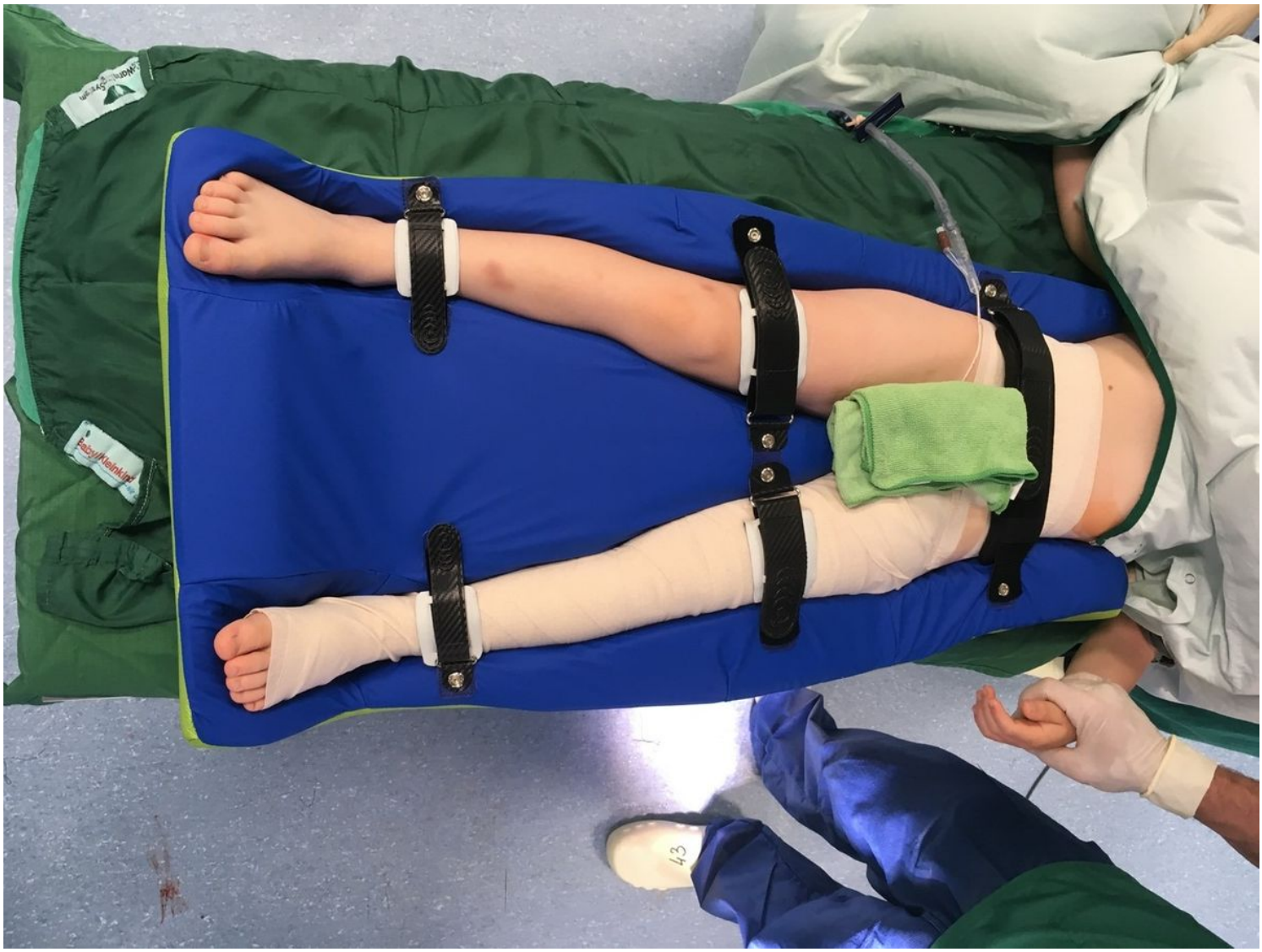

Figure 5

foam splint

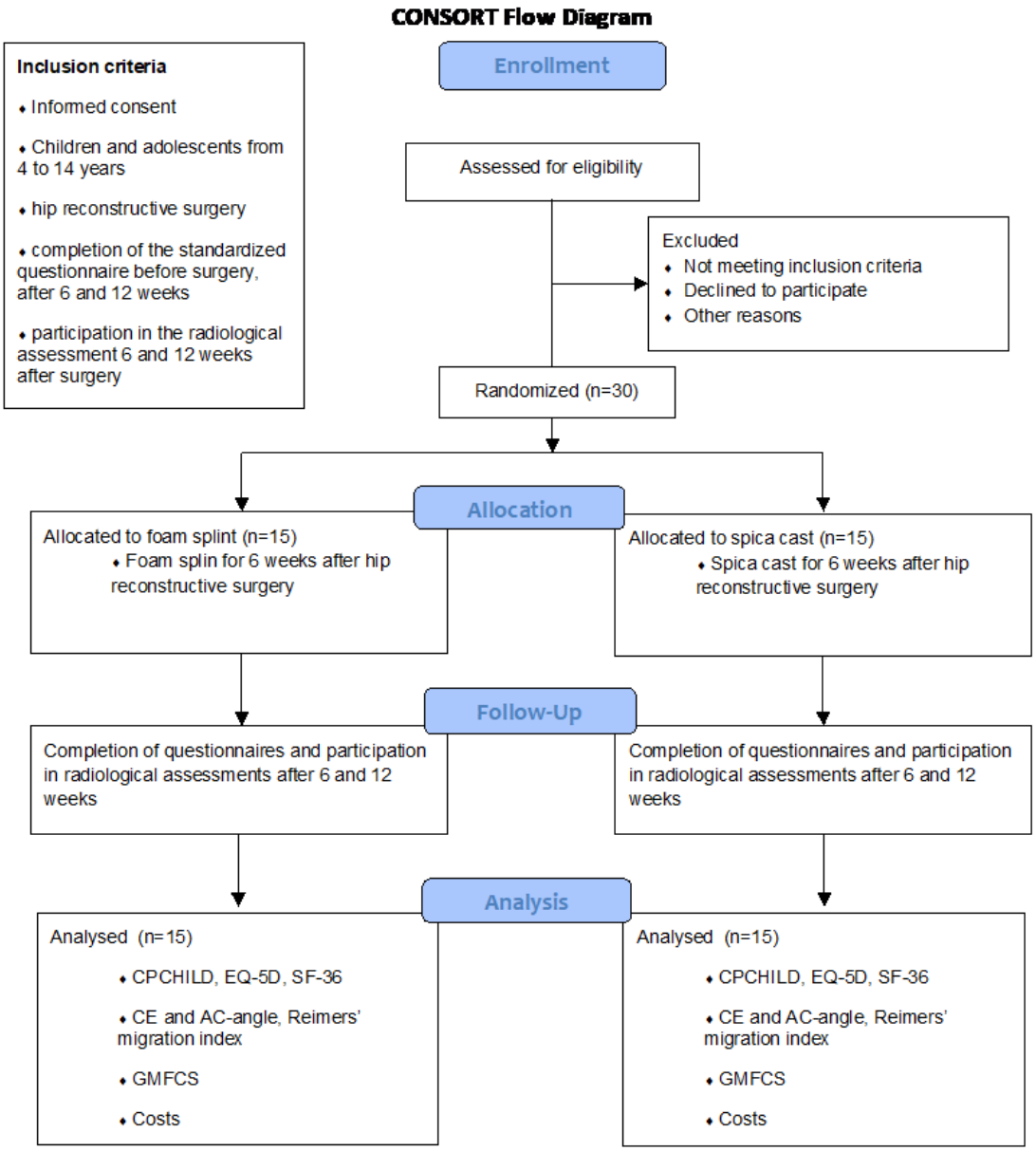

Figure 6

the algorithm of the trial

Supplementary Files

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- completedSPIRITchecklist.docx