Paediatric distal radius torus fracture treatment comparison in a prospective randomized control trial: mitella versus plaster cast

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If the study shows that the treatment with a sling gives an earlier return to normal function en does not give a clinically significant difference in pain experience compared to cast therapy than the traditional treatment can be adjusted. We aim at...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bone and joint injuries
Study type	Interventional

Summary

ID

NL-OMON43814

Source
ToetsingOnline

Brief title
Torus fracture therapy comparison

Condition

- Bone and joint injuries

Synonym
Torus fracture distal radius. Buckle fracture distal radius

Research involving
Human

Sponsors and support

Primary sponsor: Spoedeisende Hulp

Source(s) of monetary or material Support: Eigen instelling

Intervention

Keyword: Plaster cast, Sling, Torus fracture

Outcome measures

Primary outcome

Painscore (VAS 1-100): mean score day 1-4

Secondary outcome

- Painscore (VAS 1-100): mean score first week (day 1-7) and after 2 weeks.

- Wrist function with a questionnaire (0-100).

The Acitvities Scale for Kids is a validated questionnaire that has been translated [11-12]. The first questionnaire is collected at the ED and concerns the 3 previous days before the EDvisit. Other questionnaires will be collected after 1 and 2 weeks. Every questionnaire concerns the 3 previous days.

- Range of motion with goniometer (dorso- and volarflexion of the left and right wrist)

- Gripstrength (Power (kg) of the left and right hand)

The range of motion and gripstrength will be performed in the ED and after 1 and 2 weeks in the outpatient clinic.

Additional variables

- Use of pain medication (tablets/day)

- Discomfort (itching, too heavy, too tight, too wide, other complaints)

- Comfortability of the treatment (5 point scale: very comfortable to very uncomfortable)

- Satisfaction of the treatment (5 pointscale: very satisfied to very

unsatisfied)

Study description

Background summary

Torus fractures of the wrist are a common injury amongst children. It is a very simple fracture, that can easily be missed during clinical examination. An X-ray will show a buckle on te cortex of the bone. Traditionally, these simple and stable fractures are treated with a below the elbow short arm cast.
Recent studies have considered looking at treatment alternatives. These studies showed that this stable fracture does not need long term immobilsation in a cast, and that treatment with soft bandages and removable splints is a safe alternative with many benefits [1-5, 10]. S. Gryllis Allison mentioned that treatment with only a mitella and no furthur immobilsation will be enough, because the fracture is stable and studies have shown that the use of support bandages is of little of no use in promoting stability and encouraging recovery. Watts and Armstrong found that the use of support bandages does not reduce recovery time and may increase the need for analgesia in EDs [6].
Studies have shown that treatment with soft bandages or removable splints is more comfortable and that a quicker return to normal function is achieved in comparison with cast therapy [1-5, 10]. In the study of West et al. 95% of the bandage patients were able te move their wrists during the fourth day and all patiënts were using the wrist during the second week. De cast patiënts were not able to move or use the wrist until the fourt week. Concerning pain two bandage studies contradict eachother. The bandage group of West et al. had less pain and the duration of pain was shoter than that of the cast group (22% during 1-2 days versus 71% during 2-5 days). The bandage group of Kropman et al experienced more pain during the first week than the cast group, but this difference was not clinically significant (mean VAS 26 versus 20). A VAS 10-15 points difference on a 100 point scale is clinically significant [7-9].
A limitation of both studies of Kropman and West is that they defined function by volar and dorsal flexion. It is more complete to add also gripfunction and a functionquestionnaire. Also the timing of functionmeasurement (after 4 and 6 weeks) is not ideal. It is more interesting to measure after 1 and 2 weeks and finally after 6 weeks. The last limitation of Kropman is that the treatment given is longer than standard. The patiënts were ginving a cast of pressure bandage for 4 weeks. In our hospital the mean duration of treatment is 12 days.
Another limitation of the study of West is the small amount of patients and the lack of a sample size calculation.
Also the painresults are questionable. They acsertained pain or no pain. They did not grade the pain. 78% of the pressure bandage and 28% of the cast

patients experienced no pain during the first week. This seems unlikely when compared to the results of Kropman and Plint.
In our study we want to compare mitella therapy with cast therapy. This study has not been performed previously. It will test the theory that torus fractures are stable and that only symptomatic treatment is required. We expect that mitella therapy is more comfortable, gives earlier return to normal function en does not give a difference in pain experience compared to cast therapy.
When our theory is correct, than this will have considerable economic implications by money to be saved in terms of time and resource management.

Literature
1. S. West et al. Buckle fractures of the distal radius are safely treated in a soft bandage. A randomized prospective trial of bandage versus plaster cast. J. Pediatr. Orthop. Volume 25, Number 3, May/June 2005, Pag. 322-325.
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7. Powel CV et al. Determining the minimum clinically significantdifference in visual analog pain score for children. Ann. Emerg. Med. 2001;37:28-31
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Study objective

If the study shows that the treatment with a sling gives an earlier return to normal function en does not give a clinically significant difference in pain

experience compared to cast therapy than the traditional treatment can be adjusted. We aim at contributing to a national or international guideline in the future.
It is a non-inferiority study. This means that the children from the slinggroup are allowed te have a little bit more pain than the castgroup if their return to normal function is faster. They are not allowed to have clinically significant more pain than the cast group. This means a difference of 10-15 point on a 100-pointscale. If there is a clinically significant difference in pain, than the standard casttreatment will not be changed.

Study design

Randomized controlled trial (RCT), open

Intervention

Randomisation into 2 groups:
A. Sling
B. Cast + sling

Study burden and risks

There are no risks involved in this study. Both therapies are save. There are no invasive tests. Patients return 1 or 2 times at the outpatient clinic during the traditional cast therapy, every visit has an estimated duration of 15 minutes. In the study context we expect these visits to last 30 minutes.

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

Children 5 to 15 years old with:
- A torus fracture of the distal radius

Exclusion criteria

Children with:
- Greenstick fractures
- Torus antebrachii fractures
- Children with an additional fracture(s)
- Children with a metabolic bone disease
- Children with special needs
- Language barrier
- Children living in another region and therefore are followed-up in another hospital

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-11-2010
Enrollment:	108
Type:	Actual

Ethics review

Approved WMO

Date:	04-10-2010
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	04-06-2012
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	27-01-2015
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	03-05-2016
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL30801.098.10