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

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27696

Source
NTR

Brief title
Torus fracture therapy comparison

Health condition

Paediatric distal radius torus fracture

Sponsors and support

Primary sponsor: none. Funding source is our own hospital: MCH (Medisch Centrum Haaglanden)
Source(s) of monetary or material Support: MCH (Medisch Centrum Haaglanden)

Intervention

Outcome measures

Primary outcome

Painscore (VAS 1-100): Mean score day 1-4.

Secondary outcome

1. Painscore (VAS 1-100): Mean score first week (day 1-7), after 2 and 6 weeks;

2. Wrist function with a questionnaire (0-100). The Acitvities Scale for Kids is a validated questionnaire that has been translated. The first questionnaire is collected at the ED and concerns the 3 previous days before the ED visit. Other questionnaires will be collected after 1, 2 and 6 weeks. Every questionnaire concerns the 3 previous days;

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

4. Gripstrength (Power (kg) of the left and right hand) The range of motion and gripstrength will be performed in the ED and after 1, 2 and 6 weeks in the outpatient clinic. After 1 week the measurements will be done by two indepent observers to evaluate the precision of this non-validated test Additional variables;

5. Use of pain medication (tablets/day);

6. Discomfort (itching, too heavy, too tight, too wide, other complaints);

7. Comfortability of the treatment (5 point scale: very comfortable to very uncomfortable);

8. 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. 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. 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.

We will compare a group treated with a sling versus a grroup treated with a plastercast. 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. The study will be a randomized controlled trial (RCT), single blinded (The doctors who examine the patients weekly in the outpatient clinic are blinded for therapy. Slings and casts are removed by the researchers before patients enter the room of the examiner. Patiënts are instructed not to tell the type of their therapy).

Randomisation will lead to two groups: A. Sling B. Cast. The children will be treated fot two weeks with the sling or the cast. The study will last 6 weeks.

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

Day 0, day 4, 1-2-6 weeks.

Intervention

We will compare a group treated with a sling versus a grroup treated with a plastercast. 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

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A. Sling;

B. Cast.

The children will be treated fot two weeks with the sling or the cast. The study will last 6 weeks. The primary outcome score is the mean painscore of day 1-4 (VAS 1-100).

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Eligibility criteria

Inclusion criteria

1. A torus fracture of the distal radius;

2. Age 5-15.

Exclusion criteria

1. Greenstick fractures;

2. Torus antebrachii fractures;

3. Children with additional fractures;

4. Children with a metabolic bone disease;

5. Children with special needs;

6. Language barrier;

7. 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:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-11-2010
Enrollment:	108
Type:	Anticipated

Ethics review

Positive opinion

Date:	06-09-2010
Application type:	First submission

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
NTR-new	NL2400
NTR-old	NTR2508
Other	CCMO : 30801
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A