Conservative treatment of simple forearm fractures, cast versus elastic bandage (tubigrip)

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What is the function of the forearm after a torus fracture in children at an age of 4 to 10 with different immobilisation techniquesWhat is the time that children after a torus fracture are using their limb, without making use of a form of...

Ethical review Approved WMO
Status Recruiting
Health condition type Fractures

Study type Observational non invasive

Summary

ID

NL-OMON35916

Source

ToetsingOnline

Brief title

ConISA

Condition

Fractures

Synonym

buckling, Greenstick fracture, torus fracture

Research involving

Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Forearm Fracture Torus Greenstick

Outcome measures

Primary outcome

Visual Analogue Scale for pain

Secondary outcome

- function score of the Activities Scales for Kids performance version ASKp
- physical exam
- Dynamometer score
- Difference in adverse events non foreseen

Study description

Background summary

While there remains no evidence regarding the ideal method and period of treatment for stable forearm fractures like a torus fracutere. Longer imobilisation than one week is regarding the literature of no benefit, therefore a functional treatment with an elastic bandage (tubigrip) is of beneficial use. The advantage of this form of treatment is the early possibility of exercising the injuried limb, the comfort and hygiene

Study objective

What is the function of the forearm after a torus fracture in children at an age of 4 to 10 with different immobilisation techniques
What is the time that children after a torus fracture are using their limb, without making use of a form of immobilisation.

Study design

when sustaining a fracture, patient will visit the emergency department. Here the diagnoses will be made of a torus fracture. Information will be given and the child will be treated with a cast for one week.

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One week later the child will visit the outpatient clinic and the cast will be removed. An informed consent must be signed for entering participation in the study protocol. After randomisation has take place, the fracture is treated for a continuing of cast treatment for 2 more weeks or a functional treatment in which an elastic bandage (tubigrip) is offered.

During treatment contact and evaluation will take place in the same number for both groups. During hospital visits a physical exam an ASKp score and VAS score will be taken as a dynamometer test. All to evaluate function and comfort. Follow up will end after 3 months with there last visit.

Study burden and risks

Regarding the recent literature is the chance of complications neglectable. The found complications in the literature were concerned with a poor inclusion. Regarding the treatment for fractures this could now also be the case for both treatments and is not of concern for this specific study.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Children (2-11 years)

Inclusion criteria

After trauma a torus fracture of the forearm, without displacement or angulation. Patients in the age from 4 - 10 years

Exclusion criteria

Sustained dislocation with the torus fracture Children younger than 4 years and older than 10 years of age

Study design

Design

Study phase: 4

Study type: Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Treatment

Recruitment

NL

Recruitment status: Recruiting
Start date (anticipated): 28-09-2011

Enrollment: 200

Type: Actual

Ethics review

Approved WMO

Date: 25-07-2011

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

CCMO NL36643.075.11