

Conservative treatment of midclavicular fractures with Kinesio® clavicular tape and sling vs sling

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The hypothesis is that patients who receive treatment with kinesio tape and sling will experience less pain and better shoulder function compared to patients treated with only a sling.

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON28907

Bron

NTR

Verkorte titel

Conclaaf

Aandoening

clavicle, randomized controlled trial, fracture bones, quality of life

Ondersteuning

Primaire sponsor: Onze lieve vrouwe gasthuis (OLVG), Amsterdam, the Netherlands

Overige ondersteuning: Onze lieve vrouwe gasthuis (OLVG), Amsterdam, the Netherlands

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Quality of life measured by the DASH (Disabilities of the Arm, Shoulder and Hand) questionnaire

Toelichting onderzoek

Achtergrond van het onderzoek

Fractures of clavícula are frequently diagnosed. Of all fractures about 4 % are fractures of the clavícula. Of these about 75% are mid-shaft (3% of all fractures). Conservative sling treatment of the mid-shaft fractures dominates the therapeutic approach. Complications encountered with this procedure are mal-union, non-union, pain, restrictions of arm movements and cosmetic. The treatment has an acceptable prognosis with relative little additional morbidity. When focussing on quality of life after sling treatment there are still many complaints of pain, weakness of muscular strength and rapid fatigue of the arm muscles on exertion during the first weeks. A new type of elastic tape, Kinesio® clavicle tape in combination with sling treatment gave remarkable better results in a small pilot set-up. Relief of pain and better shoulder function was immediately experienced by all patients. These effects lasted the first weeks.

Tape treatment has never been compared to sling treatment in a RCT.

Doel van het onderzoek

The hypothesis is that patients who receive treatment with kinesio tape and sling will experience less pain and better shoulder function compared to patients treated with only a sling.

Onderzoeksopzet

The study will take 2 years to finish.

Onderzoeksproduct en/of interventie

The experimental group gets the Kinesio® clavicle tape application during 3 weeks in combination with sling treatment. The other group gets the sling treatment in combination with a placebo tape application.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Patients with a midclavicular fracture
2. In the age from 12 to 60 years
3. With a informed consent

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Age less than twelve or greater than sixty years
2. A pathological fracture
3. An open fracture
4. A fracture older than 28 days after injury
5. A fracture in the proximal or distal third of the clavícula
6. An associated neurovascular injury with objective neurological findings on physical

examination

7. An inability to comply with the follow-up
8. A lack of consent
9. Good understanding of dutch language by word and in writing
10. The use of psychopharmacological drugs

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland	
Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-10-2008
Aantal proefpersonen:	128
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing	
Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL672
NTR-old	NTR1374
CCMO	NL23237.100.08
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten

- Nonoperative treatment compared with plate fixation of displaced midshaft clavicular fractures. A multicenter, randomized clinical trial. J Bone Joint Surg Am 2007b; (89): 1-10. Andersen K, Jensen P O, Lauritzen J.

- Treatment of clavicular fractures. Figure-of-eight bandage versus a simple sling. Acta Orthop Scand 1987; (58): 71-74. Jeray K J.

- Acute midshaft clavicular fracture. J Am Acad Orthop Surg 2007; (15): 239-248. McKee M D, Pedersen E M, Jones C, Stephen D J, Kreder H J, Schemitsch E H, Wild L M, Potter J.

- Deficits following nonoperative treatment of displaced midshaft clavicular fractures. J Bone Joint Surg Am 2006; (88): 35-40. Zlowodzki M, Zelle B A, Cole P A, Jeray K, McKee M D.

- Treatment of acute midshaft clavicle fractures: systematic review of 2144 fractures: on behalf of the Evidence-Based Orthopaedic Trauma Working Group. J Orthop Trauma 2005; (19): 504-507.