Effectiveness of bracing patients with adolescent idiopathic scoliosis.

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Bracing patients with adolescent idiopathic scoliosis in an early stage results in at least 5 degrees less mean progression of the curvature compared to the control group after two years of follow up.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON23157

Bron
NTR

Verkorte titel
N/A

Aandoening

Adolescent Idiopathic Scoliosis (AIS)

Ondersteuning

Primaire sponsor: Erasmus MC, dept. of Public Health
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Overige ondersteuning: Netherlands Organisation for Health Research and Development (ZonMw), Stichting Nuts-Ohra, Vereniging Trustfonds Erasmus Universiteit Rotterdam

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Cobb angle, two years after inclusion.

Toelichting onderzoek

Achtergrond van het onderzoek

Each year around 300-400 adolescents are being diagnosed with progressive Adolescent Idiopathic Scoliosis (AIS, a lateral curvature of the spine), of whom half are detected by the nationwide screening programme for scoliosis at schools. AIS may lead to serious cosmetic and psychosocial problems, spine degeneration and severe forms may cause intrathoracal problems. The common early treatment for AIS is bracing, a close-fitting brace being applied to the trunk. The ultimate goal of bracing is prevention of progression and thereby surgery, which may have serious complications. A brace should be worn for 18-23 hours a day and for many years during adolescence; 70% of patients regard this treatment as (very) unpleasant. However, the effectiveness of early AIS treatment by bracing has never been demonstrated in randomised controlled trials (RCT). In practice, there is no evidence that bracing AIS patients is better than active surveillance, awaiting further progression in some patients.

In this individual RCT, 100 consecutive AIS patients with Cobb angles of 22-35 degrees will be randomised either to the intervention group, who will get brace treatment, or to the control group, who is offered regular surveillance only. At 4 months follow-up examinations, two orthopaedic surgeons will measure Cobb angles in both groups blindly and independently. Bracing will be considered effective if after 2 years of follow-up the progression of the curvature in the intervention group is at least 5 degrees less (clinically relevant), on average, compared to the control group.

Doel van het onderzoek

Bracing patients with adolescent idiopathic scoliosis in an early stage results in at least 5 degrees less mean progression of the curvature compared to the control group after two years of follow up.

Onderzoeksproduct en/of interventie

Patients in the intervention group will be treated with a brace. The brace is a device that fits closely around the body to exert pressure to the trunk in order to push the spine into a straighter position. The patients will be advised to wear the brace every day for 18-23 hours. Patients are allowed to go to physiotherapy if they want to, but this is not obligatory. Patients of the control group will initially not be braced during the two study years, unless their curvature shows more than 10 degrees progression compared to the Cobb angle at inclusion.

The patients of the control group are allowed to go to physical therapy, because physical therapy alone will not prevent further progression of the curvature.The orthopaedic surgeons willexamine all patients every four months, amongst other things by X-ray.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Eligible patients are girls and boys in the age group 8-15 years whose diagnosis of AIS has been established by an orthopaedic surgeon, who have not yet been treated by bracing or surgery and for whom further growth of physical height is still expected based on medical examination and maturation characteristics (Risser sign) established by X-ray. To expect further growth of physical height, patients only with Risser sign < 3 will be included. As agreed in the consensus by de different health professionals in the orthopaedic field, the Cobb angle should either be minimally 22 and maximally 29 degrees with established progression of more than 5 degrees or should be minimally 30 and maximally 35 degrees; progression for the latter is not necessarily established.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Patients with other forms of scoliosis (e.g. as a result of neuromuscular diseases) are excluded.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	19-01-2006
Aantal proefpersonen:	100
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	17-01-2006
Soort:	Eerste indiening

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	NL519
NTR-old	NTR563
Ander register	: ZonMw projectnumber: 945-06-354
ISRCTN	ISRCTN36964733

Resultaten

Samenvatting resultaten
N/A