Effectiveness of bracing patients with adolescent idiopathic scoliosis.

No registrations found.

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

Summary

ID

NL-OMON23157

Source
NTR

Brief title
N/A

Health condition

Adolescent Idiopathic Scoliosis (AIS)

Sponsors and support

Primary sponsor: Erasmus MC, dept. of Public Health
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Source(s) of monetary or material Support: Netherlands Organisation for Health Research and Development (ZonMw), Stichting Nuts-Ohra, Vereniging Trustfonds Erasmus Universiteit Rotterdam

Intervention

Outcome measures

Primary outcome

Cobb angle, two years after inclusion.

Secondary outcome

Quality of life, patient preferences, costs.

Study description

Background summary

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.

Study objective

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.

Intervention

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.

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Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	19-01-2006
Enrollment:	100
Type:	Anticipated

Ethics review

Positive opinion

Date:	17-01-2006
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	NL519
NTR-old	NTR563
Other	: ZonMw projectnumber: 945-06-354
ISRCTN	ISRCTN36964733

Study results

Summary results
N/A