

Effectiveness of bracing patients with adolescent idiopathic scoliosis

Submission date 14/02/2006	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 14/02/2006	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 18/08/2009	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
NTR563; ZonMw no. 945-06-354

Study information

Scientific Title

Study objectives

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.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Received from local medical ethics committee

Study design

Multicentre randomised open label active controlled parallel group trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Not Specified

Participant information sheet

Health condition(s) or problem(s) studied

Adolescent Idiopathic Scoliosis (AIS)

Interventions

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 will examine all patients every four months, amongst other things by X-ray.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Cobb angle, two years after inclusion.

Secondary outcome measures

1. Quality of life
2. Patient preferences
3. Costs

Overall study start date

19/01/2006

Completion date

31/03/2009

Eligibility**Key inclusion criteria**

1. Firls and boys in the age group 8-15 years
2. Diagnosis of AIS has been established by an orthopaedic surgeon
3. not yet been treated by bracing or surgery
4. 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.
5. As agreed in the consensus by the 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.

Participant type(s)

Patient

Age group

Child

Lower age limit

8 Years

Upper age limit

15 Years

Sex

Both

Target number of participants

100

Key exclusion criteria

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

Date of first enrolment

19/01/2006

Date of final enrolment

31/03/2009

Locations

Countries of recruitment

Netherlands

Study participating centre

Erasmus Medical Centre

Rotterdam

Netherlands

3000 DR

Sponsor information

Organisation

Erasmus Medical Centre (Netherlands)

Sponsor details

Department of Public Health

P.O. Box 1738

Rotterdam

Netherlands

3000 DR

Sponsor type

Hospital/treatment centre

ROR

<https://ror.org/018906e22>

Funder(s)

Funder type

Research organisation

Funder Name

Netherlands Organisation for Health Research and Development (ZonMw) (Netherlands)

Alternative Name(s)

Netherlands Organisation for Health Research and Development

Funding Body Type

Private sector organisation

Funding Body Subtype

Other non-profit organizations

Location

Netherlands

Funder Name

Erasmus University Rotterdam (Association trust fund [Vereniging Trustfonds]) (Netherlands)

Alternative Name(s)

Erasmus University Rotterdam, Erasmus Universiteit, EUR

Funding Body Type

Government organisation

Funding Body Subtype

Universities (academic only)

Location

Netherlands

Funder Name

The Nuts Ohra Foundation (Stichting Nuts Ohra) (Netherlands)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	Protocol	22/04/2008		Yes	No