

# Effectiveness of bracing patients with adolescent idiopathic scoliosis

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

**Protocol serial number**  
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

**Study type(s)**

Not Specified

**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(s)**

Cobb angle, two years after inclusion.

**Key secondary outcome(s)**

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

**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

## Healthy volunteers allowed

No

## Age group

Child

## Lower age limit

8 years

## Upper age limit

15 years

## Sex

All

## 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)

### 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

**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? |
|----------------------------------|----------|--------------|------------|----------------|-----------------|
| <a href="#">Protocol article</a> | Protocol | 22/04/2008   |            | Yes            | No              |