ISRCTN36964733 https://doi.org/10.1186/ISRCTN36964733

Effectiveness of bracing patients with adolescent idiopathic scoliosis

Submission date	Recruitment status	[ ] Prospectively registered
14/02/2006	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
14/02/2006	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
18/08/2009	Musculoskeletal Diseases	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Ms E.M. Bunge

Contact details
Erasmus Medical Centre
Department of Public Health
P.O. Box 1738
Rotterdam
Netherlands
3000 DR
+31 (0)10 4087498
e.bunge@erasmusmc.nl

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