

Bracing in adolescent idiopathic scoliosis trial

Submission date 04/07/2008	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 04/07/2008	Overall study status Completed	<input checked="" type="checkbox"/> Protocol
Last Edited 11/04/2019	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

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Public

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT00448448

Protocol serial number
MCT-81050

Study information

Scientific Title
Bracing in Adolescent Idiopathic Scoliosis Trial

Acronym
BrAIST

Study objectives
Bracing is an effective, non-operative treatment for adolescent idiopathic scoliosis.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Research Ethics Board of the Hospital for Sick Children (Toronto), 19/04/2004, ref: 1000010719

Study design
Blinded (outcome assessor), randomised parallel assignment trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Adolescent idiopathic scoliosis

Interventions
Amended as of 06/03/2009:
Bracing arm: Thoracolumbar spinal orthosis, worn daily until skeletal maturity or curve progression to 50 degrees
Watchful waiting arm: Physician evaluation every 6 months until skeletal maturity or curve progression to 50 degrees

Initial information at the time of registration:
Bracing arm: Thoracolumbar spinal orthosis, worn daily until skeletal maturity or curve progression greater than 45 degrees

Watchful waiting arm: Physician evaluation every 6 months until skeletal maturity or curve progression greater than 45 degrees

Intervention Type

Device

Primary outcome(s)

Amended as of 06/03/2009:

Progression to 50 degrees as measured every 6 months.

Initial information at the time of registration:

Progression to greater than 45 degrees as measured every 6 months.

Key secondary outcome(s)

1. Child Health Questionnaire measured every 6 months
2. Self-Image Questionnaire for Young Adolescents measured every 6 months
3. Peds Quality of Life measured every 6 months
4. Spinal Appearance Questionnaire measured every 6 months

Completion date

01/04/2012

Eligibility

Key inclusion criteria

Amended as of 06/03/2009:

5. Primary Cobb angle 20 - 39 degrees

Initial information at the time of registration:

1. Diagnosis of adolescent idiopathic scoliosis
2. Aged 10 - 15 years, either sex
3. Risser 0 - 2
4. Menarche within 1 year
5. Primary Cobb angle 25 - 39 degrees
6. Curve Apex caudal to T7

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Child

Lower age limit

10 years

Upper age limit

15 years

Sex

All

Key exclusion criteria

1. Other musculoskeletal, neurological, or developmental illnesses possibly responsible for the curvature
2. Physical and mental disability precluding adherence to bracing protocol
3. History of previous surgical or orthotic treatment
4. Inability to read and understand English, Spanish, and/or French

Date of first enrolment

01/04/2007

Date of final enrolment

01/04/2012

Locations**Countries of recruitment**

Canada

United States of America

Study participating centre

The Hospital for Sick Children

Toronto

Canada

M5G 1X8

Sponsor information**Organisation**

The Hospital for Sick Children (Canada)

ROR

<https://ror.org/057q4rt57>

Funder(s)**Funder type**

Research organisation

Funder Name

Canadian Institutes of Health Research (ref: MCT-81050)

Alternative Name(s)

Instituts de Recherche en Santé du Canada, The Canadian Institutes of Health Research (CIHR), Canadian Institutes of Health Research (CIHR), Canadian Institutes of Health Research | Ottawa ON, CIHR - Welcome to the Canadian Institutes of Health Research, CIHR, IRSC

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Canada

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	17/10/2013	11/04/2019	Yes	No
Protocol article	protocol	01/10/2013		Yes	No
Basic results				No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes