ISRCTN81733841 https://doi.org/10.1186/ISRCTN81733841

Bracing in adolescent idiopathic scoliosis trial

Submission date
04/07/2008

Recruitment status
No longer recruiting

Registration date
04/07/2008

Overall study status
Completed

Last Edited
11/04/2019

Condition category
Musculoskeletal Diseases

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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

Primary study design
Interventional

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

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