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Bracing in adolescent idiopathic scoliosis trial

Submission date
04/07/2008

Registration date
04/07/2008

Last Edited
11/04/2019

Recruitment status
No longer recruiting

Overall study status
Completed

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

Study website
http://www.goosetowngraphics.com/braist/index.htm

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00448448

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Patient information material on http://www.goosetowngraphics.com/braist/index.htm

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 measure
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.

Secondary outcome measures
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

Overall study start date
01/04/2007

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

Age group
Child

Lower age limit
10 Years

Upper age limit
15 Years

Sex
Both

Target number of participants
449

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)

Sponsor details
555 University Avenue
Toronto
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Sponsor type
Hospital/treatment centre

Website
http://www.sickkids.ca/

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, Canadian Institutes of Health Research (CIHR), CIHR_IRSC, Canadian Institutes of Health Research | Ottawa ON, CIHR, IRSC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Canada

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?
Basic results				No	No
Protocol article	protocol	01/10/2013		Yes	No
Results article	results	17/10/2013	11/04/2019	Yes	No