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

Study website

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

Contact information

Type(s) Scientific

Contact name Dr James Gardner Wright

Contact details

Department of Surgery The Hospital for Sick Children 555 University Avenue Toronto Canada M5G 1X8 +1 (0)416 813 6433 james.wright@sickkids.ca

Type(s)

Public

Contact name Ms Magdalena Lysenko

Contact details

Clinical Research Coordinator Hospital for Sick Children 555 University Avenue Toronto Canada M5G 1X8

magdalena.lysenko@sickkids.ca

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 Risser 0 - 2
Menarche within 1 year
Primary Cobb angle 25 - 39 degrees
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 Canada M5G 1X8

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 Basic results	Details	Date created	Date added	Peer reviewed? No	Patient-facing? No
Protocol article	protocol	01/10/2013		Yes	No
Results article	results	17/10/2013	11/04/2019	Yes	No