Actualités du traitement orthopédique des déviations rachidiennes

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Clinique du Parc - Lyon

BRAIST

Bracing in Adolescent Idiopathic Scoliosis Trial (BrAIST)

This study is currently recruiting participants.

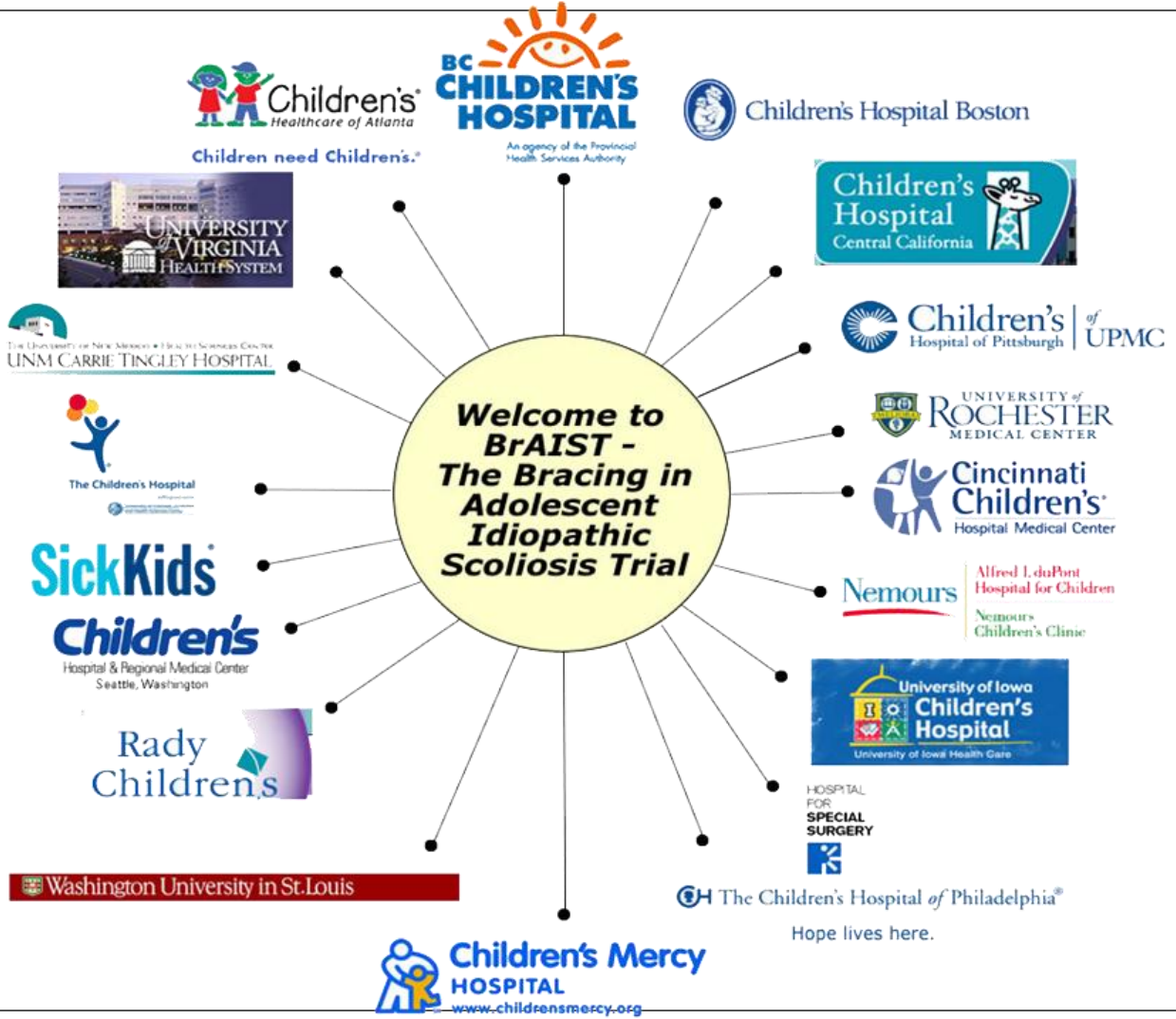
Verified by National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS), September 2009

First Received: March 14, 2007 Last Updated: September 1, 2009 History of Changes

Sponsor:	National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS)
Collaborators:	University of Iowa Canadian Institutes of Health Research (CIHR) Shriners Hospitals for Children Children's Mercy Hospital Kansas City University of Rochester
Information provided by:	National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS)
ClinicalTrials.gov Identifier:	NCT00448448

Purpose

Adolescent idiopathic scoliosis (AIS) is a structural curve of the spine with no clear underlying cause. Bracing is currently the standard of care for preventing curve progression and treating AIS. However, the effectiveness of bracing remains unclear. The purpose of this study is to compare the risk of curve progression in adolescents with AIS who wear a brace versus those who do not and to determine whether there are reliable factors that can predict the usefulness of bracing for a particular individual with AIS.


Children's Healthcare of Atlanta
Children need Children's.
BC CHILDREN'S HOSPITAL
An agency of the Provincial Health Services Authority
Children's Hospital Boston
UNIVERSITY of VIRGINIA HEALTH SYSTEM
Children's Hospital Central California
UNM CARRIE TINGLEY HOSPITAL
Children's Hospital of Pittsburgh of UPMC
The Children's Hospital
UNIVERSITY of ROCHESTER MEDICAL CENTER
Welcome to BrAIST - The Bracing in Adolescent Idiopathic Scoliosis Trial
Cincinnati Children's Hospital Medical Center
SickKids
Nemours
Alfred I. duPont Hospital for Children
Nemours Children's Clinic
Children's
Hospital & Regional Medical Center
Seattle, Washington
University of Iowa Children's Hospital
University of Iowa Health Care
Rady Children's
HOSPITAL FOR SPECIAL SURGERY
Washington University in St.Louis
The Children's Hospital of Philadelphia
Hope lives here.
Children's Mercy HOSPITAL
www.childrensmercy.org

Critères d'inclusion

Eligibility

Ages Eligible for Study: 10 Years to 15 Years
Genders Eligible for Study: Both
Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:

- Diagnosis of AIS
- Skeletally immature (Risser grade 0, 1, or 2)
- Pre-menarchal or post-menarchal by no more than 1 year
- Primary Cobb angle between 20 and 40 degrees
- Curve apex caudal to T7 vertebrae
- Physical and mental ability to adhere to bracing protocol
- Ability to read and understand English, Spanish, or French
- Documented insurance coverage and/or personal willingness to pay for treatment

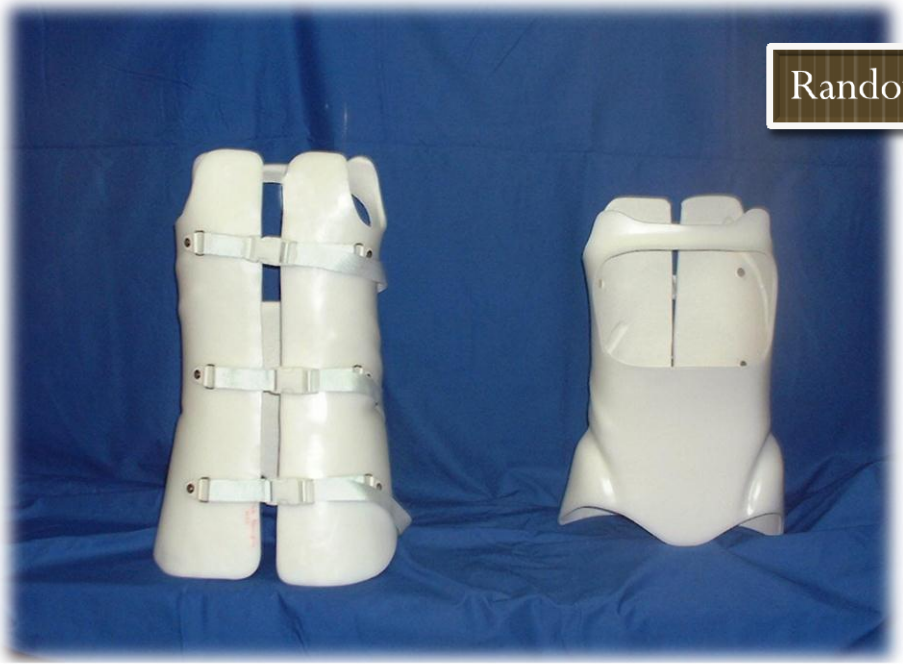
Exclusion Criteria:

- Diagnosis of other musculoskeletal or developmental illness that might be responsible for the spinal curvature
- History of previous surgical or orthotic treatment for AIS

Scoliose idiopathique de l'adolescent
Fille ou garçon
De 10 à 15 ans
Risser 0-2
Courbures entre 20° et 40°

TLSO sans plâtre préalable

RIEN



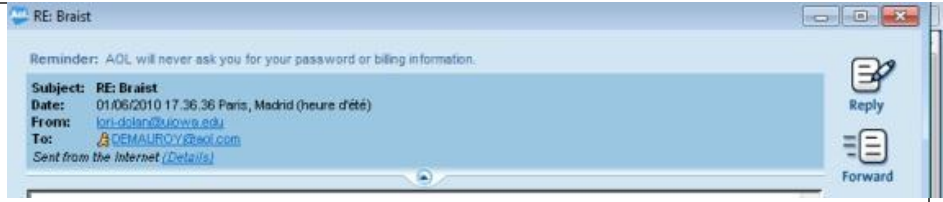
Randomisé

Porté au moins 18 heures par jour

1er bilan – août 2010

Tracking Information	
First Received Date ICMJE	March 14, 2007
Last Updated Date	September 1, 2009
Start Date ICMJE	February 2007
Estimated Primary Completion Date	August 2010 (final data collection date for primary outcome measure)
Current Primary Outcome Measures ICMJE (submitted: February 29, 2008)	• Progression of Cobb angle to greater than 50 degrees (proxy for surgical indication) [Time Frame: Measured throughout study] [Designated as safety issue: No] • Cessation of skeletal growth [Time Frame: Measured throughout study] [Designated as safety issue: No]
Original Primary Outcome Measures ICMJE (submitted: March 14, 2007)	• Progression of Cobb angle to greater than 50 degrees (proxy for surgical indication) • Cessation of skeletal growth
Change History	Complete list of historical versions of study NCT00448448 on ClinicalTrials.gov Archive Site
Current Secondary Outcome Measures ICMJE (submitted: February 29, 2008)	• Clinical measures [Time Frame: Measured every 6 months] [Designated as safety issue: No] • Radiographic measures [Time Frame: Measured every 6 months] [Designated as safety issue: No] • Psychosocial measures [Time Frame: Measured every 6 months] [Designated as safety issue: Yes]

Le mail



- Hello Dr. de Mauroy -
- Very nice to hear from you. I'm sorry I wasn't able to attend SOSORT this year.
- **My message about bracing is that there is no high level evidence supporting the hypothesis that bracing decreases curve progression to a Cobb angle of 50 degrees or greater in children at high risk for curve progression**
- This message has been supported by several systematic reviews including the recent Cochrane Collaboration report headed by Dr. Negrini.
- I would love to hear more about your study and to offer my assistance - please let me know if I can help.
- **Lori Dolan**