

Does the use of gait analysis for decision making, improve outcomes of surgery for children with cerebral palsy?

Submission date 25/02/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 08/03/2010	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 11/04/2019	Condition category Nervous System Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

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)
NCT00419432

Protocol serial number
MCT-99826

Study information

Scientific Title

Functional outcomes following orthopaedic surgery based on gait laboratory versus observational gait analysis in ambulatory children with cerebral palsy: a multicentre pilot randomised controlled trial

Study objectives

For ambulatory children with cerebral palsy (CP) who undergo multi-level lower extremity orthopaedic surgery, the addition of gait analysis for surgical decision-making compared with observational analysis alone, results in greater improvement in function and/or gait appearance 2 years after surgery.

Specific objectives of the pilot trial:

The goal of this pilot trial is to establish the feasibility of, and to provide the template for the design and implementation of the definitive large multicentre trial to answer the question above. The specific objectives include:

1. Establish the feasibility of implementing the randomised trial study design in multiple centres
2. Estimate recruitment rates and timelines
3. Establish responsiveness of outcome measures to finalise the primary and secondary outcomes
4. Estimate effect sizes of functional outcomes for sample size calculations
5. Establish data management system (web-based database) for definitive multicentre study
6. Assess feasibility, reliability and face validity of pilot health economic data forms to include health economic evaluation in the future definitive multicentre trial

Secondary objectives include:

7. Does the addition of gait analysis alter surgical decisions made from video observation alone, when performed in the setting of this pilot trial?
8. Evaluate the consistency of the surgical decision making: intra- and inter-rater reliability

Ethics approval required

Old ethics approval format

Ethics approval(s)

1. Canada: Research Ethics Board (REB) of The Hospital for Sick Children approved in October 2006 (ref: 1000009387); reviewed and approved annually
2. Canada: REB of Bloorview Kids Rehab approved in February 2007 (ref: 06-013); reviewed and approved annually

Approval pending from:

3. Canada: REB of British Columbia Children's Hospital
4. Canada: REB of Glenrose Rehabilitation Hospital
5. USA: Institutional Review Board (IRB) of the University of Wisconsin

All other centres will seek ethics approval before recruiting participants.

Study design

Multicentre patient and outcomes-assessor blinded pilot randomised controlled clinical trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Cerebral palsy

Interventions

Children allocated to Group A (controls) will undergo orthopaedic surgery based on the physical examination and observational analysis of the gait alone, while children allocated to Group B (experimental) will undergo orthopaedic surgery using the physical examination, observational and the gait laboratory analysis data.

Treatment in this case is an assessment (gait, PT and questionnaires lasting approximately 4 hours) at baseline, 6, 12 and 24 months follow-up. The exact same procedures apply to each arm of the study (it is the information from the gait assessment that may or may not be given to the surgeon depending on randomisation), therefore any child on the study can expect to participate for 24 months.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

1. Gross Motor Function Measure (GMFM-66)
2. Gillette Gait (Normalcy) Index (GGI)
3. Pediatric Outcomes Data Collection Instrument (PODCI)
4. Functional Assessment Questionnaire (FAQ)
5. Functional Mobility Scale (FMS)
6. Activities Scale for Kids (ASK-performance)
7. Gait Parameters: gait velocity and stride length

The final primary and secondary outcome measures will be chosen based on responsiveness and their effect sizes used to calculate sample size for the definitive trial

Key secondary outcome(s)

Consistency of Surgeons' Decision Making: intra- and inter-rater reliability

The final primary and secondary outcome measures will be chosen based on responsiveness and their effect sizes used to calculate sample size for the definitive trial

Completion date

01/08/2013

Eligibility**Key inclusion criteria**

1. Diagnosis of spastic cerebral palsy
2. Age 6 to 15 years at the time of the initial assessment, either sex

3. Gross Motor Function Classification System (GMFCS) levels II or III (demonstrable independent ambulatory potential with or without orthotics/assist devices)
4. Patients have been referred for assessment and treatment of gait abnormality
5. Patients have a gait abnormality interfering with their physical function
6. Patients are candidates for orthopaedic surgery including soft tissue and/or bony procedures involving at least 2 levels, in one or both lower extremities (e.g. knee and ankle)
7. Patients must be able to undergo instrumented gait analysis testing in a motion laboratory

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Child

Lower age limit

6 years

Upper age limit

15 years

Sex

All

Key exclusion criteria

1. Presence of dystonia, athetosis, or mixed tone abnormalities
2. History of orthopaedic lower extremity procedures within the previous 2 years
3. Patients who have had previous gait laboratory analysis that has been seen by the treating surgeon
4. Patients who will be unable to return for the required follow up visits/gait analysis

Date of first enrolment

01/03/2010

Date of final enrolment

01/08/2013

Locations**Countries of recruitment**

Canada

United States of America

Study participating centre

Division of Orthopaedic Surgery

Toronto

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Sponsor information

Organisation

Bloorview Kids Rehab (Canada)

ROR

<https://ror.org/03qea8398>

Funder(s)

Funder type

Research organisation

Funder Name

Canadian Institutes of Health Research (CIHR) (Canada) - <http://www.cihr-irsc.gc.ca> (ref: MCT-99826)

Funder Name

Bloorview Children's Hospital Foundation (Canada)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration