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

Submission date	Recruitment status	[ ] Prospectively registered
25/02/2010	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
08/03/2010	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
11/04/2019	Nervous System Diseases	[ ] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00419432

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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 measure
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

Secondary outcome measures
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

Overall study start date
01/03/2010

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

Age group
Child

Lower age limit
6 Years

Upper age limit
15 Years

Sex
Both

Target number of participants
50

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
Canada
M5G 1X8

Sponsor information

Organisation
Bloorview Kids Rehab (Canada)

Sponsor details
150 Kilgour Road
Toronto
Canada
M4G 1R8

Sponsor type
Hospital/treatment centre

Website
http://www.bloorview.ca

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

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