The effect of leg inequality on pelvic and hip kinematics in children

Submission date 25/01/2018	Recruitment status No longer recruiting	[X] Prospectively registered [_] Protocol
Registration date 01/02/2018	Overall study status Completed	
Last Edited 30/01/2018	Condition category Musculoskeletal Diseases	 Individual participant data Record updated in last year

Plain English summary of protocol

Background and study aims

Unequal leg length affects between 40% and 70% of the population and is classified into two groups: a) anatomical discrepancy, when the inequality is caused by a difference in the length of the bones and can affect children from birth, and b) functional discrepancy, when the inequality is caused by muscle tightness or weakness. It is thought that having legs of different lengths alters the way in which children walk and is thought to cause pain, lower back problems and arthritis in the future. Alder Hey Children's Hospital Orthopaedic department has a regional limb reconstruction service where children with leg length inequality is detrimental to the child and may lead to problems in the future, but it is invasive and comes with associated risks. There is a gap in the current knowledge and only two studies were found which investigated the effect of unequal leg length on walking in children, and both identified that walking was altered but did not specify how. Modern medicine should be evidence based, therefore this study aims to provide information to inform surgeons on the impact of leg length inequality on children, which may help inform surgical decision making.

Who can participate?

Children aged 7 to 16 who have undergone 3D gait analysis as part of their routine clinical care

What does the study involve?

As part of their routine clinical care children are assessed in the North Movement Analysis Centre, Alder Hey using the 3D gait analysis system. At the time of assessment informed consent is taken allowing technical and clinical information to be used for research. It is this anonymised information which is used for the study, requiring no further attendance by the children.

What are the possible benefits and risks of participating?

The study will add to the limited knowledge base by providing data on gait compensations in children with leg length discrepancy. This in turn may inform appropriate surgical management in the future. There are no risks to the participants as their data is collected as part of routine clinical care. Written parental consent is provided at the time of assessment.

Where is the study run from? North West Movement Analysis Centre (UK)

When is the study starting and how long is it expected to run for? February 2018 to May 2018

Who is funding the study? Investigator initiated and funded

Who is the main contact? Mr Paul McGrath paul.mcgrath@alderhey.nhs.uk

Contact information

Type(s) Public

Contact name Mr Paul McGrath

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Additional identifiers

EudraCT/CTIS number

IRAS number 237648

ClinicalTrials.gov number

Secondary identifying numbers IRAS project ID: 237648

Study information

Scientific Title

What is the effect of an idiopathic leg length discrepancy on coronal plane pelvis and hip kinematics in children during walking?

Study objectives

The study hypothesis is that there will be a change in pelvic and hip coronal plane gait kinematics in children with a leg length discrepancy compared to normal gait kinematics. The change that occurs will be increased pelvic obliquity and associated increased hip adduction on the longer side.

Ethics approval required

Old ethics approval format

Ethics approval(s) Ethics Board London-Bromley, 12/01/2018, REC ref: 18/LO/0093

Study design Retrospective case control study

Primary study design Observational

Secondary study design Case-control study

Study setting(s) Hospital

Study type(s) Other

Participant information sheet

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

Health condition(s) or problem(s) studied

Idiopathic leg length discrepancy

Interventions

This retrospective case control study will analyse coronal plane pelvic and hip kinematic data during normal walking in children with a leg length discrepancy (>2cm defined radiologically). Prior to 3D data capture all patients undergo a full lower limb physical exam comprising of leg length measurement, range of movement measurement using goniometry and muscle strength testing. 3D gait data is collected as part of routine clinical care using a 12 camera 340Hz 3D gait analysis system and BTS Smart Capture software (BTS Bioengineering, Milan). 22 reflective markers are placed on patients in line with the conventional gait model Davis heel protocol. Subjects walk at a self-selected speed across a 10 metre walk way and a minimum of 6 walking trials are collected. For data analysis, data from 5 trials are selected for processing using BTS Smart Analyser software; 1 gait cycle per left and right leg is manually defined. Data from the 5 trials are then averaged generating single kinematic graphs for the left and right legs. Coronal plane pelvic and hip kinematic data from each subject that has been converted to text files will be added to a database containing the data of all participants. Data is anonymised and participants will be given unique identifiers prior to input into the database. Mean pelvic and hip kinematics for the participant sample will be generated and compared to the NWMAC normal database. Correlation between leg length discrepancy and gait abnormality at the pelvis and hip will be investigated.

Intervention Type

Other

Primary outcome measure

Coronal plane joint range of motion at the pelvis and hip, measured in degrees using a 3D gait analysis system. The measurements are obtained once at the patients attendance at the North West Movement Analysis Centre, Alder Hey as part of their routine clinical care.

Secondary outcome measures

The amount of leg length discrepancy as a percentage of total height (leg length is measured using a tape measure and recorded in centimetres) at the time of attendance at NWMAC

Overall study start date

05/02/2018

Completion date 25/05/2018

Eligibility

Key inclusion criteria

- 1. Aged between 7 to 16 years
- 2. Undergone 3D gait analysis as part of their routine clinical care
- 3. Written parental consent for their data to be used for research purposes
- 4. No previous orthopaedic surgery

Participant type(s)

Patient

Age group

Child

Lower age limit 7 Years

Upper age limit

16 Years

Sex Both

Target number of participants A minimum of 10 participants

Key exclusion criteria

- 1. Neurological disorder
- 2. Hip pathology
- 3. Hip muscle contractures
- 4. Hip pain

5. Fixed scoliosis
 6. Spinal pathology

Date of first enrolment 05/02/2018

Date of final enrolment 16/02/2018

Locations

Countries of recruitment England

United Kingdom

Study participating centre North West Movement Analysis Centre Alder Hey Children's NHS Foundation Trust Eaton Road Liverpool United Kingdom L12 2AP

Sponsor information

Organisation University of Salford

Sponsor details School of Health Sciences Brian Blatchford Building Manchester England United Kingdom M6 6PU

Sponsor type University/education

ROR https://ror.org/01tmqtf75

Funder(s)

Funder type Other

Funder Name Investigator initiated and funded

Results and Publications

Publication and dissemination plan

Study protocol and statistical analysis will be available on completion of the study (May 2018). The plan is for the study to be published in the Gait and Posture journal around one year after the overall trial end date/project completion. The study will also be freely available to the Chartered Society of Physiotherapy who may wish to publish the study in their Physiotherapy Journal, as well as the Association of Paediatric Chartered Physiotherapists Journal.

Intention to publish date

25/05/2019

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Paul McGrath (paul.mcgrath@alderhey.nhs.uk).

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No