Knee cap dislocation and mode of movement in babies

Submission date 03/01/2019	Recruitment status No longer recruiting	Prospectively registered	
		[] Protocol	
Registration date 07/01/2019	Overall study status Completed	[] Statistical analysis plan	
		[] Results	
Last Edited	Condition category	Individual participant data	
11/01/2019	Injury, Occupational Diseases, Poisoning	[] Record updated in last year	

Plain English summary of protocol

Background and study aims

Malformation of the grove within which the knee cap articulates is known as trochlea dysplasia. It is the most significant risk factor for dislocation of the knee cap, been present in >85% of patients with this. There remains no consensus on the cause. In the hip, one of the risk factors for malformation of the socket with which the thigh bone articulates (developmental dysplasia of the hip) includes things that happen soon after birth such as how the baby is carried and whether or not this allows the thigh bone to adequately impress on the socket. As such, there is a greater likelihood of developing developmental dysplasia of the hip in babies carried with hips extended compared to hips astride. It may be therefore that events soon after birth that affect whether or not the knee cap imprints on the trochlea also affect trochlea development. Infants differ in their method of early mobilisation. They may crawl, which places direct pressure on the knee cap likely causing it to imprint the trochlea. They may however bottom shuffle or go straight to walking. These do not place direct pressure on the knee cap, and may therefore result in an increased risk of trochlea dysplasia, which would result in a greater chance of dislocating the knee cap in later life. The aim is to find out if there is an increase in the likelihood of knee cap dislocation among people that were bottom shufflers and/or straight to walkers compared to those that crawled. Walking also changes the dynamics operating between the knee cap and the trochlea. A secondary aim will be to find out if there is any relationship between age of onset of independent walking and knee cap dislocation in later life.

Who can participate?

Patients identified retrospectively who have had an MRI scan of their knee in the last three years at university hospitals Birmingham.

What does the study involve?

A questionnaire shall be used for both the study and control groups.

What are the possible benefits and risks of participating?

No direct benefits to participants anticipated. Possible risks; Participants contact details shall be accessed without prior consent in order to contact them about the study.

Where is the study run from? University Hospital Birmingham, Heartlands, Solihull and Good Hope hospitals. Heartlands is the lead site

When is the study starting and how long is it expected to run for? June 2018 to December 2020

Who is funding the study? Funded by chief investigator; Bamikole Ogunwale

Who is the main contact? Bamikole Ogunwale bamikole_ogunwale@hotmail.com

Contact information

Type(s) Public

Contact name Dr Bamikole Ogunwale

Contact details

Radiology Department Birmingham Heartlands Hospital Bordesley Green East Birmingham United Kingdom B9 5SS

Type(s)

Scientific

Contact name Mr Bamikole Ogunwale

Contact details

Radiology Department Birmingham Heartlands Hospital Bordesley Green East Birmingham United Kingdom B9 5SS

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers 2017092RD

Study information

Scientific Title

Transient patella dislocation and mode of early mobilisation

Acronym EMS & TPD

Study objectives

Determine if the mode of mobilisation used by babies pre-walking influences risk of patella dislocation in later life.

Ethics approval required Old ethics approval format

Ethics approval(s)

East Midlands - Leicester South Research Ethics Committee, 02/01/2018, ref. 17/EM/0445

Study design Case controlled study, single centre, observational

Primary study design Observational

Secondary study design Case-control study

Study setting(s) Hospital

Study type(s) Prevention

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied

Transient patella dislocation

Interventions

Participants shall be identified via a search of the radiology database using keywords. Questionnaires shall then be sent to participants asking them to identify their mode of mobilisation before walking and age at which they started walking. There will be no follow-up.

Intervention Type

Other

Primary outcome measure

The type of early mobilisation used by patients with transient patella dislocation will be measured using a questionnaire developed for this study.

Secondary outcome measures

The age of independent walking (age at which first five unaided steps were taken) in patients with transient patella dislocation. will be determined using a questionnaire.

Overall study start date 11/06/2018

Completion date 31/12/2019

Eligibility

Key inclusion criteria

Age 10 to 35 years
Transient patella dislocation on MRI in last 3 years
Able to read English

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Participant type(s) Patient

Age group Mixed

Sex

Both

Target number of participants 100

Key exclusion criteria N/A

Date of first enrolment 21/07/2018

Date of final enrolment 31/12/2019

Locations

Countries of recruitment England

United Kingdom

Study participating centre Birmingham Heartlands Hospital Birmingham Heartlands Hospital Bordesley Green East Birmingham United Kingdom B9 5SS

Study participating centre Solihull Hospital Lode Lane Solihull United Kingdom B91 2JL

Study participating centre Good Hope Hospital Rectory Road Sutton Coldfield United Kingdom B75 7RR

Sponsor information

Organisation University Hospitals Birmingham

Sponsor details

Research and Development Birmingham Heartlands Hospital Bordesley Green East Birmingham England United Kingdom B9 5SS

Sponsor type Hospital/treatment centre

ROR

https://ror.org/014ja3n03

Funder(s)

Funder type Other

Funder Name Investigator initiated and funded

Results and Publications

Publication and dissemination plan

Plan to publish in a peer reviewed journal depending on results. Plan to present at relevant scientific meetings depending on results.

Intention to publish date

21/12/2021

Individual participant data (IPD) sharing plan

The data sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

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