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Knee cap dislocation and mode of movement in babies

Submission date	Recruitment status	[ ] Prospectively registered
03/01/2019	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
07/01/2019	Completed	[ ] 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
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Type(s)
Scientific

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

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
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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