Multiple Hereditary Exostosis and its daily hassles

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The purpose of this study is to find out which common problems occur in the HME patient population. Furthermore the study will investigate which factors are associated with the observed problems. This is barely investigated in the current literature...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Musculoskeletal and connective tissue disorders congenital
Study type	Observational non invasive

Summary

ID

NL-OMON44220

Source
ToetsingOnline

Brief title
MHE and its daily hassles

Condition

- Musculoskeletal and connective tissue disorders congenital
- Skeletal neoplasms benign

Synonym
benign bonetumour, Multiple Osteochondromas

Research involving
Human

Sponsors and support

Primary sponsor: Onze Lieve Vrouwe Gasthuis
Source(s) of monetary or material Support: geen vergoeding;eigen afdeling financiert onderzoek

Intervention

Keyword: health-related quality of life, Multiple Hereditary Exostosis, Multiple Osteochondromas, Rare disease

Outcome measures

Primary outcome

Quality of live scores, painscores, fatiguescores, activitylevels, mental

well-being scores.

Secondary outcome

Factors that are associated with the primary study parameters, such as: age,

seks, age of first surgery, amount of surgeries, education level, marital

status, employment status.

Study description

Background summary

Multiple Hereditary Exostosis (MHE) is a rare autosomal inherited skeletal disorder characterized by the presence of numerous bony outgrowths, also called osteochondromas. These osteochondromas can in some cases transform into chondrosarcomas. MHE manifests at a young age and gives a lot of different complications where in most cases surgery is needed. MHE affects the young and the old, therefore it is of great importance to perform this study on the total patient group. Up till now a lot of research focuses on the surgical treatment. Little attention has been paid to the effects of MHE on the physical and psychosocial well-being of the patients.

Study objective

The purpose of this study is to find out which common problems occur in the HME patient population. Furthermore the study will investigate which factors are associated with the observed problems. This is barely investigated in the current literature. With the findings of this study, we will be a step closer to developing treatment plans that cover the overall well-being of HME patients.

Study design

Study design: This is an observational study using an online survey. Patients with MHE will be informed about this study at the orthopedic outpatient clinic of the OLVG. The National Patient Association will also display information about this study on their website. In case of interest and after informed consent/assent is given, the patients will receive an email with a secured link which will give them acces to the survey. The questionnaires on the survey include 5 categories which are age-dependent: fatigue, pain, quality of life, activity level, mental well-being. The survey will take 18-78 minutes to complete. The survey can be completed on different computers, at various time points, and at participants own pace as data will be saved automatically

Study burden and risks

There are no risks associated with this study. The only burden for this study is the time invested in completing the questionnaires, 18-78 min. However due to are design of the survey this burden can be alleviated because it is possible for the subject to pause the questionnaire and complete it at another time in their own pace. Furthermore, the patients can fill in the survey in the comfort of their own homes.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)

Inclusion criteria

Individuals with multiple hereditary exostosis (MHE).
Individuals with MHE between 4 untill 17 years old.

Exclusion criteria

Individuals under the age of 4 years or older than 17 years.
Individuals who do not speak Dutch

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	17-06-2019
Enrollment:	150
Type:	Actual

Ethics review

Approved WMO

Date:	06-11-2017
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL62341.100.17