Sports Participation and Injuries in Patients with Haemophilia

Published: 04-04-2018
Last updated: 15-04-2024

Primary objectives:1. To quantify physical activity, sports participation and exposure according to age, haemophilia severity and joint status;2. To assess the incidence of sports-related injuries in those who participate in sports at least once...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Coagulopathies and bleeding diatheses (excl thrombocytopenic)
Study type	Observational non invasive

Summary

ID

NL-OMON50696

Source
ToetsingOnline

Brief title
SPRAIN

Condition

- Coagulopathies and bleeding diatheses (excl thrombocytopenic)
- Joint disorders

Synonym
Bleeding disorder, sports injury

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Bayer,een investigator grant van Bayer healthcare

Intervention

Keyword: Clotting Factor Consumption, Haemophilia, Sports Injuries and bleeds, Sports Participation

Outcome measures

Primary outcome

1. Sports participation Including type, duration, frequency and level.

- Sports is defined as "all forms of physical activity which, through casual or organised participation, aim at expressing or improving physical fitness and mental well-being, forming social relationships or obtaining results in competition at all levels."

- Type of sports will be collected using the Modified Activity Questionnaire (MAQ) for children and adults.

- Duration and frequency will be collected using the accelerometers and activity diary that we will ask our participants to complete.

- Level is described as the number of training and game sessions per week:

1. untrained (*1x/week),

2. recreationally trained (1-2x/week)

3. trained (3x/week)

4. well-trained (>4-5x/week)

5. professional (>5x/week).

For those performing sports at least once per week and participating in injury registration, duration and frequency per week will be recorded for every season (spring, summer, fall, winter), as sports participation varies throughout the

year.

2. Sports Injuries: including nature, location, severity, mechanism, date.

Sports injuries will be collected using a standardized form. Participants will be contacted by the researcher every two weeks via their preferred method.

In case of a reported injury, a standardized form will be completed by the researcher to collect detailed, specific injury data. Participants will be actively followed by to researcher to document any injuries.

Nature: Bone, joint, ligament, muscle, etc.
Location: Anatomical
Severity: Total time loss from work/school and sports participation
Mechanism: Description of the originating trauma/overload; predefined mechanisms
Risk categories: Sports will be classified according to the risk classifications used by the National Hemophilia Foundation (NHF). This classification consists of 5 categories in which sports are classified reflecting the risk of acute injury or collision that can be expected while participating in a specific activity:
1. Safe
1.5 Safe to moderate risk

2 Moderate risk

2.5 Moderate risk to dangerous

3 Dangerous

Secondary outcome

Bleeding data:

- Bleeding

- Joint bleed

- Soft-tissue bleed

- Re-bleed (after an initial moderate to excellent response to treatment, a new

bleed (both joint and soft-tissue) is defined as a bleed occurring >72 h after

stopping treatment for the original bleed for which treatment was initiated.

All other bleeds will be considered new bleeds).

Study description

Background summary

Physical activity is part of a healthy lifestyle and promotes general well-being. In addition, regular physical exercise is especially recommended for patients with haemophilia to increase muscle strength and bone density and maintain muscle mass.

As overexertion and high impact sports are considered to increase the risk of (joint) bleeding, patients with haemophilia were usually advised to limit themselves in engaging in low-impact sports like swimming and cycling. In the setting of intensive treatment, most patients with severe haemophilia have gradually become more active in many different sports, including those considered to increase bleeding risk, such as soccer. This had lead to concerns about an increased bleeding risk on one hand, on the other hand it has lead to criticism from society and some haemophilia consultants.

Data on associated bleeding risk or sport related injuries and the role of consumption and timing of FVIII/FIX administration in injuries is currently

lacking. It is important to increase our knowledge in this area to be able to improve our advises regarding sports, exercise and injury prevention for patients with haemophilia.

Study objective

Primary objectives:
1. To quantify physical activity, sports participation and exposure according to age, haemophilia severity and joint status;
2. To assess the incidence of sports-related injuries in those who participate in sports at least once every week;
3. To compare the incidence of sports-related injuries to the general male population;
4. To assess the association of sports-related injuries with physical fitness and motor proficiency.

Secondary objectives:
1. To assess/model the association between FVIII/IX activity at the time of bleeding due to sports injuries and the time of administering of clotting factor, independent of age, presence of arthropathy, motor proficiency and physical fitness.

Study design

For assessment of sports participation: cross-sectional observational single-centre study.
For assessment of the association of sports participation and FVIII/IX levels with sports-related injuries and bleeding: observational single-centre cohort study with one year follow-up.

Study burden and risks

Patient risks are considered minimal as this will be an observational study without any invasive measurements. Patient burden will consist of completing two questionnaires (±20 minutes), a single test session of physical fitness and motor proficiency (±1.5 hour), wearing an accelerometer (1 week, 8-12 hours per day), completing sports diaries during this same period (5 minutes per day) and reporting sports injuries (5 minutes per week).

Questionnaires will be completed during regular clinic visits, or will be sent home to the participants. If possible, assessments of physical fitness and motor proficiency will be performed on days that patients visit the clinic for their regular visits. Only if this is not possible, participants will be asked to visit the clinic once for the physical fitness and motor proficiency assessments. To limit travel time and demands on the participants, participating patients that do not have an appointment at the clinic within a

reasonable period will be given the opportunity to be tested in their region of habitat.

The procedures for testing patients externally will be identical to those when tested at the UMC Utrecht: based on the results of the MAQ, patients are deemed eligible for participation or not. In case of an eligible patient, their physician or physiotherapist at the van Creveldkliniek will ask whether the patient is interested in participating in this study. When a patient is interested, the investigator will send a patient information form with informed consent form for more information (see section 9.6: 'recruitment and consent*). The investigator will contact the patient after 2 weeks to answer any questions and to ask whether the patient is willing to participate in the study. In case of an external test site, this is explicitly communicated with the patient.

The testing procedure on location is identical to the procedure described in section 7.3 of the protocol (*study procedures*). Quality of the testing is warranted because the same protocol, same equipment (which is transported from the UMC Utrecht) and same researcher will be used during the external measurements. The protocol is unaltered and will be identical to the one used in the UMC Utrecht. The only thing that changes is the location. These locations will be private physiotherapy clinics, thereby assuring safety to the participants due to the demands placed on these practices. It needs to be stressed that the clinics that will be used will not be part of the study, we will only use their location and facilities

Participants will be asked to wear accelerometers on a daily basis for a period of maximal 1 week. During this period, it's important to wear these devices for at least seven consecutive days. An accelerometer is a small (approximately 3x3x1 cm) and light (approximately 20 grams) device that is worn at the hip.

Contacts

Public
Universitair Medisch Centrum Utrecht

Heidelberglaan 100
Utrecht 3584 CX
NL
Scientific
Universitair Medisch Centrum Utrecht

Heidelberglaan 100
Utrecht 3584 CX

NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Children (2-11 years)
Elderly (65 years and older)

Inclusion criteria

For cross-sectional assessment of sports participation (questionnaires): all haemophilia A and B patients with factor VIII/IX levels of 0-30% aged 6 to 65 years (N<= ±450), For the longitudinal follow-up (sports participation and FVIII/IX levels with sports-related injuries and bleeding): all patients with severe, moderate or mild haemophilia A or B (factor VIII/IX levels of 0-30%), aged 6 to 47 years (born between 1-1-1970 and 31-12-2011), who are engaged in (organised) sports at least once per week (N<= ±200).

Exclusion criteria

Refusal to participate or provide informed consent;
Presence of inhibitory antibodies against FVIII or FIX;
Arthroplasty or arthrodesis within the last 12 months.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	03-10-2018
Enrollment:	450
Type:	Actual

Ethics review

Approved WMO Date:	04-04-2018
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	28-02-2019
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	05-06-2019
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	15-01-2020
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	26-05-2020
Application type:	Amendment
Review commission:	METC NedMec

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	NL62291.041.17