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In Haemophilia patients: 1. Sports participation is dependent on age, joint status, perceived limitations and severity of haemophilia; 2. Sports participation is lower than sports participation in the general population/age matched, healthy peers...

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

Bron

NTR

Verkorte titel

SPRAIN

Aandoening

Haemophilia, sports participation, sports injuries, factor consumption, physical activity

Ondersteuning

Primaire sponsor :	University Medical Center Utrecht, Van Creveldkliniek
Overige ondersteuning :	Bayer

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

- To quantify physical activity (PA), sports participation and exposure according to age, haemophilia severity and joint status;

- To assess the incidence of sports-related injuries in those who participate in sports at least once every week;

- To compare the incidence of sports-related injuries to the general male population.

- To assess the association of sports-related injuries with physical fitness and motor proficiency.

Toelichting onderzoek

Achtergrond van het onderzoek

Regular physical exercise is recommended for patients with haemophilia (PWH) 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 traditionally 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 are now engaging in many different sports, including those considered to increase bleeding risk, such as soccer. Although data on participation in sports are increasing, data on associated bleeding risk or sport related injuries is currently lacking.

Primary objective for this study is to assess sports participation as well as bleeding and/or injuries associated with sports participation, including a comparison to the general population and association with clotting factor levels. Secondary objectives is to assess/model the effect of FVIII/IX activity at the time of bleeding due to sports injuries, independent of age, presence of arthropathy, motor proficiency and physical fitness.

Doel van het onderzoek

In Haemophilia patients:

1. Sports participation is dependent on age, joint status, perceived limitations and severity of haemophilia;

2. Sports participation is lower than sports participation in the general population/age matched, healthy peers;

3. Sports (related) injuries are different from those in the general population/age matched

healthy peers;

4. The dose of FVIII/IX prophylaxis and timing of administration in relation to sporting events are associated with sports injury risk;

5. Joint health status, physical fitness and motor proficiency are associated with the occurrence sports injuries.

Onderzoeksopzet

Data collection (cross-sectional and follow-up): 24 months

Data analysis: 6 months

Reporting: 6 months

Onderzoeksproduct en/of interventie

This study consists of a cross-sectional baseline study in which sports participation and perceived limitations are studied.

Based on the outcomes of these questionnaires, participants will be selected (moderate of severe haemophilia A or B, aged 6-47, actively engaged in sports at least once per week) for a prospective follow-up study.

In this follow-up, there will be a cross-sectional test for aerobic endurance and motor proficiency, followed by a one year follow-up in which sports activity will be assessed objectively (accelerometers) and subjectively (training diaries), while sports injuries will be recorded by the researcher.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

All patients with haemophilia A or B (FVIII/IX levels 0-30%), aged 6-65 years, treated at the Van Creveldkliniek.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Refusal to participate or provide informed consent;

- Presence of inhibitory antibodies against FVIII or FIX;

- Recent surgery: arthroplasty or arthrodesis within the last 12 months.

Onderzoeksopzet

Opzet

Type :	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel :	Parallel
Toewijzing :	Geen controle groep
Blindering :	Open / niet geblindeerd
Controle :	Geneesmiddel

Deelname

Nederland

Status :	Werving nog niet gestart
(Verwachte) startdatum :	01-11-2017
Aantal proefpersonen :	600
Type :	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum :	24-10-2017
Soort :	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL6555
NTR-old	NTR6769
CCMO	NL69221.041.17

Resultaten