

Koordinationsstelle Forschung am Menschen

BEISPIELSTUDIE

Prevalence of cam and pincer-type deformities revealed by hip MRI in asymptomatic young Swiss females: a cross-sectional study

KATEGORISIERUNG

Gattung

Forschungsprojekt mit lebenden Personen

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Nicht als klinischer Versuch geltendes Forschungsprojekt (i.d.R. Beobachtungsstudie)

Unterart

BACKGROUND

Femoroacetabular impingement may cause early osteoarthritis (OA) in the non-dysplastic hip. This study determined the prevalence of both femoral and acetabular types of impingement in young females.

METHODS

We conducted a population-based cross-sectional study of asymptomatic young females. All participants completed a set of questionnaires and had their hips clinically examined. A random sample of women was subsequently invited for contrast enhanced magnetic resonance images (MRI) of the hip (contrast media injected intra-articularly). MRIs were read to detect cam-type deformities, increased acetabular depths, labral lesions, and impingement pits. We estimated the prevalence of cam-type deformities and increased acetabular depth, and the relationships between deformities and signs of joint damage.

CATEGORISER-FRAGEN

Fällt das Forschungsprojekt in den Geltungsbereich des Humanforschungsgesetzes? Ja

BECAUSE

This project was based on a study protocol that defined the exact procedures to be used. The study included a relatively large number of persons, and was not based on individual cases ("method-driven search for generalizable knowledge", defined as research by HRA). Healthy women ("persons") completed a set of questionnaires and their hips clinically examined. The goal was to determine the prevalence of cam-type deformities ("research concerning the structure and function of the human body").

Handelt es sich bei dem Forschungsprojekt um ein Projekt mit lebenden Personen?

Ja

BECAUSE

Healthy women ("persons") were included, in this research project.

Handelt es sich bei dem Forschungsprojekt um einen klinischen Versuch im Sinne der KlinV oder der KlinV-Mep?

Nein

BECAUSE

Healthy women ("persons") completed a questionnaire and had their hips clinically examined. Investigators used magnetic resonance images (MRI) of the hip with contrast agent to determine the prevalence of camtype deformities ("diagnostic measure") in a random sample of participants. This project involved no health-related interventions (according to ClinO). MRI was the study-related procedure ("diagnostic measure") used to examine the hip. It was not employed to investigate its effects on health or on the structure and function of the human body" of MRI.

Werden im Forschungsprojekt Massnahmen angewendet welche für die teilnehmenden Personen mit minimalen Risiken und Belastungen verbunden sind?

Nein

BECAUSE

Healthy women completed a questionnaire and had their hips clinically examined. The investigators used magnetic resonance images (MRI) of the hip and contrast agent to determine the prevalence of cam-type deformities in a random sample of participants.

Werden im Forschungsprojekt Massnahmen angewendet welche für die teilnehmenden Personen mit mehr als minimalen Risiken und Belastungen verbunden sind?

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BECAUSE

Healthy women completed a questionnaire and had their hips clinically examined. We used magnetic resonance images (MRI) of the hip and contrast agent to determine the prevalence of cam-type deformities in a random sample of participants. Magnetic resonance image and contrast agent are invasive procedures and are more than minimally risky and burdensome for participants.