

Device for the screening of knee osteoarthritis (OA)

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Knee OA is characterized by the presence of crepitus (knee sounds). Therefore, this device is able to record these sounds, while the subject is doing a knee movement, and screen for the presence or absence of osteoarthritis.

Ethische beoordeling	Positief advies
Status	Anders
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON21535

Bron

Nationaal Trial Register

Verkorte titel

OASense

Aandoening

Knee osteoarthritis

Ondersteuning

Primaire sponsor: Highly individualized Patient Projects (HiPP): research consortium between Delft University of Technology (TUDelft), Reinier de Graaf Hospital and Zimmer Biomet

Overige ondersteuning: HiPP research consortium

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The measurements will be compared to X-ray data, with the aim of validating the device as a diagnostic tool for knee OA

Toelichting onderzoek

Achtergrond van het onderzoek

Affecting nearly 10% of the population worldwide, Osteoarthritis (OA) is the most common degenerative disorder, with that of the knee having the largest burden. When the patient feels symptoms associated to OA, such as pain or swelling, he goes to the GP, who performs some physical examination and refers the patient to the orthopaedist if needed. However, a more exact diagnostic method seems to be missing in this primary healthcare.

Thus, OASense is a screening device designed for the diagnosis of knee Osteoarthritis based on the detection of crepitus (knee sounds), having GPs as its main target group. This study aims to validate the working principles of this device by means of data acquisition on healthy participants and knee OA patients.

Doel van het onderzoek

Knee OA is characterized by the presence of crepitus (knee sounds). Therefore, this device is able to record these sounds, while the subject is doing a knee movement, and screen for the presence or absence of osteoarthritis.

Onderzoeksopzet

One time measurement for each patient

Onderzoeksproduct en/of interventie

Using of the device for the recording of knee sounds on the knee surgery

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

OA patients:

Age > 18 years

Willing to participate

Have X-ray data with diagnosed OA

Non-affected participants:

Age > 18 yrs

Willing to participate

No knee-related symptoms such as pain or instability

No history of major knee joint trauma or pathologies

No previous invasive clinical treatment of the knee joint

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

OA patients:

Present surgical history, such as total knee replacement

Presenting or with history of other knee articular diseases (e.g. Rheumatoid Arthritis)

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blinding:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland	
Status:	Anders
(Verwachte) startdatum:	28-05-2018
Aantal proefpersonen:	40
Type:	Onbekend

Ethische beoordeling

Positief advies	
Datum:	22-05-2018
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	NL7032

Register

NTR-old

Ander register

ID

NTR7237

METC Zuidwest Holland : 18-054

Resultaten