# Device for the screening of knee osteoarthritis (OA)

No registrations found.

| | |
|---|---|
| **Ethical review** | Positive opinion |
| **Status** | Other |
| **Health condition type** | - |
| **Study type** | Observational non invasive |

## Summary

### ID

NL-OMON21535

**Source**
NTR

**Brief title**
OASense

**Health condition**

Knee osteoarthritis

### Sponsors and support

**Primary sponsor:** Highly individualized Patient Projects (HiPP): research consortium between Delft University of Technology (TUDelft), Reinier de Graaf Hospital and Zimmer Biomet
**Source(s) of monetary or material Support:** HiPP research consortium

### Intervention

### Outcome measures

**Primary outcome**

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

### Secondary outcome

None

## Study description

### Background summary

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.

### Study objective

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.

### Study design

One time measurement for each patient

### Intervention

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

## Contacts

**Public**
Reinier de Graafweg 3-11
N.M.C. Mathijssen
Delft 2525 AD
The Netherlands

+31 (0)15 2603718
**Scientific**
Reinier de Graafweg 3-11
N.M.C. Mathijssen
Delft 2525 AD
The Netherlands
+31 (0)15 2603718

# Eligibility criteria

## Inclusion criteria

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

## Exclusion criteria

OA patients:

Present surgical history, such as total knee replacement
Presenting or with history of other knee articular diseases (e.g. Rheumatoid Arthritis)

# Study design

## Design

Study type: Observational non invasive

| | |
|---|---|
| Intervention model: | Parallel |
| Allocation: | Non controlled trial |
| Masking: | Open (masking not used) |
| Control: | N/A , unknown |

### Recruitment

NL

| | |
|---|---|
| Recruitment status: | Other |
| Start date (anticipated): | 28-05-2018 |
| Enrollment: | 40 |
| Type: | Unknown |

## Ethics review

Positive opinion

| | |
|---|---|
| Date: | 22-05-2018 |
| Application type: | First submission |

## 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 |
|---|---|
| NTR-new | NL7032 |
| NTR-old | NTR7237 |
| Other | METC Zuidwest Holland : 18-054 |

## Study results