Applied Public-Private Research enabling OsteoArthritis Clinical Headway study * a 2-year multicentre, European, exploratory study without therapeutic benefit in patients with knee osteoarthritis to describe, validate, and predict phenotypes of knee osteoarthritis by use of clinical, imaging, and biochemical (bio)markers.

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To prospectively describe in detail pre-identified progressing phenotypes of patients with knee OA by use of conventional and novel clinical, imaging, and biochemical (bio)markers, and to validate and refine a predictive algorithm for these (and new...

Ethical review	Approved WMO
Status	Completed
Health condition type	Joint disorders
Study type	Observational invasive

Summary

ID

NL-OMON48924

Source
ToetsingOnline

Brief title
APPROACH

Condition

- Joint disorders

Synonym
knee osteoarthritis

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: AbbVie,GlaxoSmithKline,IMI,Merck,Servier

Intervention

Keyword: biomarkers, imaging, knee osteoarthritis, phenotypes

Outcome measures

Primary outcome

Progression of osteoarthritis measured by joint tissue structure based on

radiographs, MRI, and biochemical (bio)markers as well as symptoms (pain,

function) and quality of life by questionnaires.

Secondary outcome

a multitude of (novel and conventional) clinical, maging, and biochemical

parameters related to osteoarthritis.

Study description

Background summary

Despite a large and growing disease burden in osteoarthritis (OA), many pharmaceutical companies have abandoned OA drug development mainly due to the lack of appropriate outcome measures that can robustly identify patients that can benefit from a specific therapy.

Study objective

To prospectively describe in detail pre-identified progressing phenotypes of patients with knee OA by use of conventional and novel clinical, imaging, and biochemical (bio)markers, and to validate and refine a predictive algorithm for these (and new) progressing phenotypes based on these markers.

Study design

APPROACH is an exploratory, European, five-centre, 2-year prospective follow-up, cohort study, with extensive measurements.

Study burden and risks

The participants will not have any direct benefit from their participation in this study other than that their OA is maximally diagnosed and followed in detail for up to 2 years (screening, baseline, 6 months, 12 months, 24 months). Patients will stay in the hospital for 4-5 hours per visit (for screening about 30 min) for physical examination, blood draw, MRI scans, radiographs of knees and hands (only at baseline and 24 months), CT scan of the knee (only at baseline and 24 months), low radiation whole body CT scan (only at baseline and 24 months), HandScan (only at baseline and 24 months), motion analysis and performance based tests. They will be asked to fill out questionnaires about knee, hand and hip osteoarthritis, and about general health and pain. The patient council in the consortium indicated that the load is acceptable. The patient council will be involved in the execution of the study.
The assumed risk is minimal for an individual patient and minimal compared to the contribution to the development of knowledge of their disease. These risks include minimal events due to blood sampling itself (such as hematoma or localized bleeding), roentgen exposure by radiographic imaging techniques (with a minimal increased healthcare risk), and exposure to MRI techniques (without known risks and without use of contrast agents).

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1. Ambulatory (able to walk unassisted)
2. At least 18 years of age
3. Capable of understanding the study
4. Capable of writing and reading in local language
5. Predominantly tibiofemoral knee osteoarthritis and satisfy the clinical classification criteria of the American College of Rheumatology (ACR): Knee pain and three of the following criteria: over 50 years age, less than 30 minutes of morning stiffness, crepitus on active motion, bony tenderness, bony enlargement, or no palpable warmth.
6. Informed consent obtained as described in section 12.3 of the protocol.
7. Highest probability to progress based on a selection algorithm based on the following criteria:
- KOOS questionnaire
- BMI (in recording height and weight)
- Pain NRS of the index knee at the moment of the screening visit
- Pain NRS of the index knee during the last week before the screening visit
- Age
- Gender
- KIDA parameters of the index knee, based on standardized weight-bearing (KIDA) radiograph, measured < 3 months (patients with a JSW < 2 mm of the index knee will not be included)

Exclusion criteria

8. Not being able to comply to the protocol
9. Participating in a trial with local therapeutic intervention for index knee OA (pharmaceutical or surgical) or systemic DMOADs or potential DMOADs treatments for OA at the same time or within the past 6 months or anticipated in the forthcoming; participation in non-interventional registries or epidemiological studies is allowed.
10. Surgery of the index knee in the past 6 months (to avoid interferences with imaging)
11. Scheduled or expected surgery of the index knee in the next 2 years (to avoid interferences with imaging)
12. Pregnancy (child bearing woman) because of imaging (radiation and MRI, risks), 13. Predominantly patellar femoral knee OA
14. The following secondary osteoarthritis of the knee: clinically significant deformities of the lower limbs (varus >10°, valgus >10°), septic arthritis, inflammatory joint disease, gout, major chondrocalcinosis (pseudogout), Paget*s disease of the bone, ochronosis, acromegaly, haemochromatosis, Wilson*s disease, rheumatic symptoms due to malignancies, primary osteochondromatosis, osteonecrosis, osteochondritis dissecans, haemophilia
15. Generalized pain syndrome, for example fibromyalgia
16. Patients with contra indication to MRI or CT
17. Hip replacement or expected hip replacement within 6 months
18. Self-reported severe spine OA

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	19-01-2018
Enrollment:	210

Type:	Actual

Ethics review

Approved WMO Date:	11-09-2017
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	25-07-2018
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	06-01-2020
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	NL61405.041.17

Study results

Date completed:	03-04-2021
Results posted:	19-08-2022

First publication
19-08-2022