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A new method to objectively observe the function of orthopaedic patients

Submission date	Recruitment status	[ ] Prospectively registered
30/05/2007	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
30/05/2007	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
25/10/2021	Musculoskeletal Diseases	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr R. Senden

Contact details
Hoogstraat 229
Voeren
Belgium
B-3798
+32 (0)62 3043131
rachel.senden@bw.unimaas.nl

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
NL942 (NTR967)

Study information

Scientific Title
A new method to objectively observe the function of orthopaedic patients

Study objectives
The use of an objective device (accelerometer) to analyse function is more accurate than the currently used methods (observing by eyes).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Received from the local ethics committee (METC Atrium MC - Maaslandziekenhuis). The commitee concluded on the 26th March 2007 that the research is not WMO- obligated and permission was granted.

Study design
Observational study

Primary study design
Observational

Secondary study design
Case-control study

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet

Health condition(s) or problem(s) studied
Orthopaedic patients, accelerometer

Interventions
An accelerometer, attached to the sacrum of the subject using an elastic belt, measures accelerations in three directions when the doctor observes the patient as usual (walk ability, sit to stand, balancing, etc). The objective outcome will be compared with the doctors observation and questionnaires.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure

Parameters which give information about the function of the patient like walk speed, asymmetry during walking, postural sway during balancing etc. These will be measured at the end of the doctors investigation.

Secondary outcome measures
Patient data like weight, height, date of birth and the health state of the patient is collected. These will be measured at the end of the doctors investigation.

Overall study start date
15/05/2007

Completion date
01/05/2008

Eligibility

Key inclusion criteria
All orthopaedic patients visiting the policlinic of the orthopaedic department of the Atrium Medical Centre Heerlen.

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
100

Key exclusion criteria
Unable to perform the tasks (walking, balacing, rising from a chair, step on a block).

Date of first enrolment
15/05/2007

Date of final enrolment
01/05/2008

Locations

Countries of recruitment
Belgium

Netherlands

Study participating centre
Hoogstraat 229
Voeren
Belgium
B-3798

Sponsor information

Organisation
Atrium Heerlen Orthopaedic Research and Scientific Education (AHORSE) (The Netherlands)

Sponsor details
Atrium Medical Centre
P.O. Box 4446
Heerlen
Netherlands
6401 CX

Sponsor type
Hospital/treatment centre

Website
http://www.atriummc.nl/#http://www.atriummc.nl/

ROR
https://ror.org/0367sye10

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Atrium Medical Centre (The Netherlands)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Not provided at time of registration