TEMPLATE RESEARCH PROTOCOL

(September 2018)

- May 2015: adaptation section 11.5: text in accordance to old and new Measure regarding Compulsory Insurance for Clinical Research in Humans
- Sept 2015: adaptation section 9.1, 9.2 and 12.5: text in accordance to WMO amendment on reporting SAE and temporary halt (section 10 of WMO)
- Oct 2015: adaptation section 4.4 – comment [CCMO15], 8.2 and 10.1 with respect to methodology/statistics
- Sept 2018: adaptation section 12.1 and comment [CCMO46] due to applicability GDPR as of May, 2018

PROTOCOL TITLE

Physical activity in patients after resurfacing and total hip arthroplasty: an observational follow-up study 15 years after surgery.

Protocol ID	2025-2605
Short title	Triaxial Accelerometry Study
EudraCT number	N/A
Version	1
Date	11-02-2025
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Sponsor (Dutch: 'Verrichter')	Stichting Rijnstate Ziekenhuis Afdeling Orthopedie (1191) Antwoordnummer 111 6800 WC Arnhem
Subsidising party	**N/A**
Independent expert (s)	**N/A**
Study Sites	Department of Orthopedics, Rijnstate Hospital, Arnhem, The Netherlands. MSK Laboratory, Imperial College London, United Kingdom.
Pharmacy	**N/A**

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LIST OF ABBREVIATIONS AND RELEVANT DEFINITIONS

AE	**Adverse Event**
CCMO	**Central Committee on Research Involving Human Subjects; in Dutch: Centrale Commissie Mensgebonden Onderzoek**
DLW	**Doubly Labelled Water**
DSMB	**Data Safety Monitoring Board**
EU	**European Union**
EudraCT	**European drug regulatory affairs Clinical Trials**
GDPR	**General Data Protection Regulation; in Dutch: Algemene Verordening Gegevensbescherming (AVG)**
IC	**Informed Consent**
IPAQ-SF	**International Physical Activity Questionnaire - Short Form**
METC	**Medical research ethics committee (MREC); in Dutch: medisch-ethische toetsingscommissie (METC)**
MVPA	**Moderate-to-vigorous physical activity**
OHS	**Oxford Hip Score**
PA	**Physical Activity**
PAEE	**Physical activity energy expenditure**
RHA	**Resurfacing Hip Arthroplasty**
(S)AE	**(Serious) Adverse Event**
Sponsor	**The sponsor is the party that commissions the organisation or performance of the research, for example a pharmaceutical company, academic hospital, scientific organisation or investigator. A party that provides funding for a study but does not commission it is not regarded as the sponsor, but referred to as a subsidising party.**
SQUASH	**Short Questionnaire to Assess health-enhancing physical activity**
THA	**Total Hip Arthroplasty**
UCLA	**University of California at Los Angeles**
UK	**United Kingdom**
WMO	**Medical Research Involving Human Subjects Act; in Dutch: Wet Medisch-wetenschappelijk Onderzoek met Mensen**

SUMMARY

Rationale:

Arthritis significantly impacts patients' lives, affecting everything from pain and fatigue to daily activities and overall mortality. Physical activity (PA), particularly moderate-to-vigorous physical activity (MVPA), is crucial in managing arthritis symptoms and reducing mortality risks, with even minimal MVPA providing significant health benefits. Wearable technology has revolutionized the measurement of physical activity, offering accurate, large-scale data that informs treatment efficacy. Despite this, little is known about how common arthritis treatments affect physical activity levels, highlighting a critical gap in our understanding. Joint replacement, while effective in reducing pain and improving function, shows varying long-term mortality outcomes, suggesting the need for further research into how different surgical procedures impact patients' activity levels and overall well-being.

Objectives: i) To compare the volume and intensity of physical activity 15 years after surgery in patients after hip resurfacing and total hip replacement and ii) to explore the association between the participants' physical activity and functional outcome scores.

Study design: A cross-sectional observational (follow-up) study.

Study population: We will approach patients that have previously participated in a randomised controlled trial during which they received either hip resurfacing (*n* = 34) or total hip replacement (*n* = 26).

Intervention (if applicable): In this study there is no intervention, only observation using accelerometers. Participants will be asked to compete four physical activity questionnaires. Subsequently, they will wear a tri-alaxial accelerometer on their non-dominant wrist continuously for ten days and nights, and simultaneously wear a tri-axial accelerometer taped to the surgical thigh for a period of 48 hours.

Main study parameters/endpoints: Using the accelerometers we will measure the participants' physical activity energy expenditure (PAEE), the intensity distribution of PAEE and step count. Secondary outcomes include self-reported physical activity, health status and the ability to perform specific activities.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: There is no risk associated with participating in this study. Patients will be asked to complete four paper questionnaires at home (duration: 15 minutes). Patients will also be asked to wear an accelerometer on their wrist for ten days, and to simultaneously wear one accelerometer on their surgical thigh for 48 hours. The accelerometers collect physical activity data automatically.

1. INTRODUCTION AND RATIONALE

1.1 Arthritis and physical activity

The impact of arthritis is wide-ranging and patient specific. From traditional symptoms such as fatigue and pain to more holistic considerations like holiday destination and pragmatism over style(1), arthritis affects many patient life domains. Treatment strategies are similarly broad - spanning lifestyle changes, medicine, and surgery - as is the definition of what constitutes success in treatment. Surveys of arthritis sufferers have identified a reduction in fatigue, pain and a return to normal activities as core expectations of this patient group(1),(2), but again, answers are highly personal. Yet beyond commonly reported symptoms, some forms of arthritis are associated with a shortened life span. For example, a 15-year prospective study of rheumatoid arthritis patients in the Netherlands revealed significantly higher all-cause mortality in rheumatoid patients (3). Likewise, lower limb osteoarthritis is associated with increased cardiovascular mortality (4) and all-cause mortality (5). Further, gait speed, which commonly decreases with end-stage arthritis, independently predicts mortality in the elderly (6). Recent population-based studies suggest that a lack of physical activity may explain, at least in part, these findings. Physical activity researchers are ever more aware of the importance of physical activity volume and intensity in healthy ageing, both for all-cause mortality and intermediate disease states (7),(8),(9),(10),(11),(12). In a population-based study of over 96,000 participants, Strain et al. demonstrated that physical activity volume and intensity are independently associated with all-cause mortality (7). Figure 1 Illustrates this relationship, but it also highlights the additional benefit of accumulating a greater fraction of physical activity energy expenditure (PAEE) from moderate-to-vigorous physical activity (MVPA).

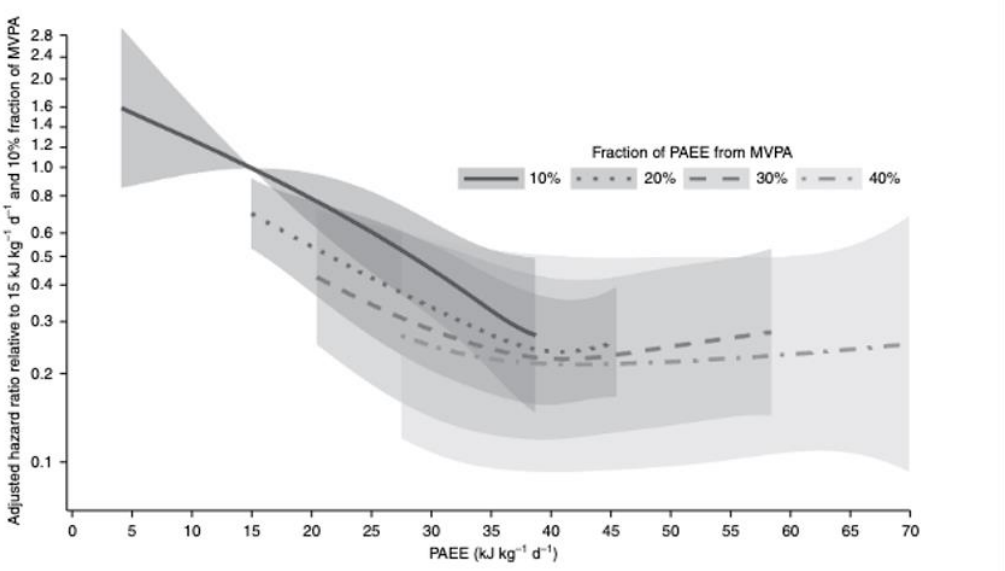

Figure 1. PAEE, intensity and all-cause mortality (7).

This study (7) demonstrated participants with the lowest levels of PAEE had almost double the mortality risk of those with average levels of physical activity. Even at low levels of physical activity, those with 20% MVPA had a 30% lower mortality rate than those with 10% MVPA. For context, this is the equivalent of a 12-minute stroll versus a brisk 7-minute walk. These findings are further supported by the results of a systematic review and meta-analysis of 30 million participants, confirming that significant protection against chronic disease is derived from just 10 minutes of MVPA per day (9). Further population-based studies have demonstrated similar associations with intermediate disease states, including obesity and cardiometabolic risk score, along with depression and anxiety (8),(12),(13). Given the sweeping benefits of physical activity, it is perhaps not surprising that markers of physical activity such as 'performing daily activities with ease', frequently rate second to pain and/or fatigue in studies of patient hopes for arthritis treatment (1),(2),(14),(15). By logical extension, it is evident that for a notable proportion of arthritis patients, treatment can only be successful if it empowers that patient to achieve their desired level of activity. Despite this, relatively little is known about the effect of common arthritis treatments on levels of physical activity. Even less is known about the intensity distribution of patients following treatment. This represents a core knowledge gap in our evaluation of the treatments provided.

1.2 Wearables and physical activity

Until the introduction of wearables, physical activity was difficult to measure objectively or at scale. Traditionally, PA was studied using subjective measures such as surveys or diaries, or extremely expensive or intrusive objective measures such as doubly labelled water (DLW) or indirect calorimetry (16),(17),(18). The former methods can be applied in large population cohorts but are known to be subject to bias (17),(19). The latter provide highly accurate information about energy expenditure but provide no information about the underlying energy distribution (intensity) of that energy expenditure (20).

The advent of wearable technology has revolutionised the study of physical activity at a population level. A variety of estimation techniques, ranging from uniaxial accelerometers to combined heart rate and movement sensors, have been used to study a diverse range of population cohorts (11),(21),(22),(23),(24). As a result, physical activity researchers have been able to look beyond simple metrics like time in MVPA to more biologically based phenomena. This has seen a shift from descriptive to aetiological studies that link an individual's average daily PAEE, or their underlying intensity composition, with disease states (25),(26),(27).

Of the methods currently available, triaxial accelerometers such as the GENEActive Device (Activinsights, UK; Figure 2) are emerging as a favoured device amongst physical activity researchers. Compared to other methods, the devices are well tolerated, can be placed on a variety of sites throughout the body, are worn 24 hours a day, are relatively inexpensive,

reusable, and are validated against the gold standard DLW in a British population (22),(28). Furthermore, as wrist-worn devices, they are suitable for use in orthopaedic patients with previous lower limb arthroplasty. Alternative devices include the thigh-worn Axivity AX3 3-Axis Logging Accelerometer (Axivity, UK; Figure 3). These are versatile, lightweight devices that have been validated against other monitors (29).

Figure 2. GENEActive triaxial accelerometer (Activinsights, UK)

Figure 3. Axivity AX3 3-Axis Logging Accelerometer (Axivity, UK)

1.3 Physical activity and common treatments for severe arthritis

Joint replacement is widely heralded as a safe and effective option for patients with end-stage arthritis, as patients report improved function and less pain. However, the statistic used to describe the success of the procedure is that of ‘implant survival’, which specifically ignores the more important metric of ‘patient survival’ (30). The two graphs below, from the National Joint Registry of England and Wales, illustrate this paradox: Figure 3A shows the unattractive higher mortality risks associated with total knee replacement, while Figure 3B shows the attractive low risk of revision surgery for the procedure.

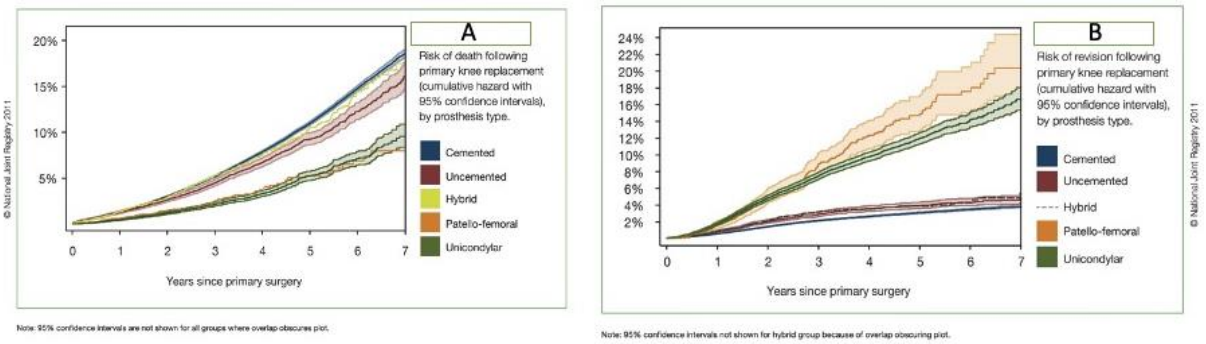

Figure 3. Implant and patient survival post-knee replacement (30).

In earlier work from our group, we have published the substantial differences in gait characteristics between patients with different types of surgical procedures (31),(32),(33). However, any extrapolation from these small laboratory-based studies would be theoretical. Our best explanation for the profound difference in mortality, in the longer term, between more and less radical procedures is that patients who are allowed to retain more of their own bodies feel more normal and thus enjoy more activity. Alternatively, patients with large stiff metal implants substituting large parts of their femur and tibia are not expected to feel 'normal' ever again. To test this explanation, we propose to study physical activity of two groups of patients who participated in a previous study (34). In the current study, we want to explore whether physical activity levels varies between these two groups 15 years after their index surgery.

2. OBJECTIVES

2.1 Primary Objective:

To compare the volume and intensity of physical activity 15 years after surgery in patients after hip resurfacing and total hip replacement.

2.2 Secondary Objective(s):

To explore the association between the participants' physical activity and functional outcome scores.

3. STUDY DESIGN

This is a cross-sectional observational (follow-up) study in which we will ask participants to complete four paper questionnaires, wear a tri-axial accelerometer on their non-dominant wrist continuously for ten days and nights, and simultaneously wear a tri-axial accelerometers taped to the surgical thigh for a period of 48 hours.

4. STUDY POPULATION

We will only approach patients that have participated in a previous randomised controlled trial (34) that was conducted in Rijnstate hospital between 2007-2008. These include 34 patients after hip resurfacing and 26 patients after total hip replacement.

5. TREATMENT OF SUBJECTS

N/A.

6. INVESTIGATIONAL PRODUCT

N/A.

7. NON-INVESTIGATIONAL PRODUCT

During this study, the participants will be asked to continuously wear two different types of accelerometers that will measure their physical activity.

GENEActiv triaxial accelerometer (wrist-worn)

We will ask the participants to wear the GENEActiv triaxial accelerometer (Activinsights, UK) on their wrist for ten consecutive days and nights. The GENEActiv is currently a Class I self-certified medical device under the MDD 93/42/EEC for CE Marking. GENEActiv is transitioning to the new Medical Device Regulation (EU) 2017/745 in 2023. Under the MDR the GENEActiv will become a Class IIa medical device.

Axivity AX3 Logging tri-axial accelerometer (thigh-worn)

We will also ask the participants to wear an Axivity AX3 Logging tri-axial accelerometer taped to the surgical thigh for a period of 48 hours. This accelerometer conforms to several EU regulation directives (89/336/EEC Electromagnetic Compatibility Directive, amended by 92/31/EEC & 93/68/EEC 72/23/EEC Low Voltage Equipment Directive, amended by 93/68/EEC). The product also meets the following standards: EN61326-1:2006 Electrical Equipment for Measurement, Control and Lab use, Radiated Emissions EN 55011:1998 A1 A2, Electrostatic Discharge EN 61000/4/2:1995 A1 A2 and Radiated Immunity EN 61000/4/3:2002.

Both types of accelerometers have been deemed safe to use on the following basis:

- They have a self enclosed, non-replaceable, 3.7V Lithium Polymer Cell.
- The products have no sharp edges.
- The products do not contain explosive, toxic or volatile parts.

All the relevant testing has been completed to ensure the device complies to the above standards. The technical documentation required to demonstrate that the product meets the requirements of the Low Voltage Directive is available for inspection by the relevant enforcement authorities. The Axivity AX3's CE mark was first applied in December 2011.

8. METHODS

8.1 Study parameters/endpoints

8.1.1 Main study parameter/endpoint

In order to gain insight into the volume and intensity of physical activity, both the wrist-worn GENEActiv triaxial accelerometer and the thigh-worn Axivity AX3 Logging tri-axial accelerometers will measure physical activity energy expenditure (PAEE) (7) and the intensity distribution of PAEE (7),(8). The wirst worn GENEActiv triaxial accelerometer will additionally measure the participants' step count (28),(35).

8.1.2 Secondary study parameters/endpoints

Prior to wearing the accelerometers we will ask the participants to complete a total of four questionnaires:

1. A Dutch version of the International Physical Activity Questionnaire - Short Form (IPAQ-SF) (36),(37),(38),(39),(40). This is a self-reported physical activity questionnaire. This questionnaire can be found in Appendix A.
2. A validated Dutch version of the Short Questionnaire to Assess health-enhancing physical activity (SQUASH). This is also a self-reported physical activity questionnaire. This questionnaire can be found in Appendix B.
3. A psychometrically sound Dutch version of the EQ-5D-5L (41),(42),(43),(44),(45). This questionnaire evaluates health status in the five dimensions of mobility (ability to walk about), self-care (ability to take care of personal hygiene and activities of daily living), usual activities (ability to perform usual activities, such as work, study, housework, family or leisure activities), pain/discomfort and anxiety/depression. This questionnaire can be found in Appendix C.
4. Finally, we will ask the participants to complete a validated Dutch version of the The Oxford Hip Score (OHS).(46),(47),(48),(49) This questionnaire includes 12 questions about the patient's ability to perform specific activities such as walking, climbing stairs, and putting on shoes and socks, as well as their experience of pain and limitations in daily activities due to their hip condition. This questionnaire can be found in Appendix D.

8.2 Randomisation, blinding and treatment allocation

In this observational (follow-up) study participants will *not* be randomised, blinded or treated. The potential participants for this current study have previously participated in a randomised controlled trial. In this RCT (34), a total of 82 patients were randomly assigned to receive resurfacing hip arthroplasty (RHA, *n* = 34) with a 6-mm thick cobalt-chromium cup or conventional total hip arthroplasty (THA, *n* = 26) with a more conical threaded titanium cup. All participants of this previous RCT will be contacted to ask if they are willing to participate in this follow-up study.

8.3 Study procedures

8.3.1 Wearing GENEActiv Triaxial Accelerometer & Axivity AX3 Logging Triaxial Accelerometers

Participants in this study will be sent both accelerometers by post. Participants will be asked to wear both the GENEActiv triaxial accelerometer for ten days and nights on their non-dominant wrist and the Axivity AX3 Logging tri-axial accelerometer on their surgical thigh for 48 hours, respectively. Both accelerometers are programmed to start at a certain time. The accelerometers are waterproof and should be worn continuously including during showering and sleeping. After use, the participants are requested to return both accelerometers to the researcher into a padded pre-paid envelope as soon as possible so the researcher can download the data. The envelope can be posted into a normal post box.

8.3.2 Instructions for wearing the accelerometers

We will provide all participants with an instruction leaflet explaining how the accelerometers should be used. This leaflet also contains a weblink to a video explaining how to wear the accelerometer: www.mrc-epid.cam.ac.uk/geneactiv1. Although this video is in English, in combination with the Dutch written instructions these should be easy to understand. The instruction leaflet also contains a phone number that participants can call in case they have questions or need assistance in placing or using the accelerometers.

8.4 Withdrawal of individual subjects

Subjects can leave the study at any time for any reason if they wish to do so without any consequences. The investigator can decide to withdraw a subject from the study for urgent medical reasons.

8.5 Replacement of individual subjects after withdrawal

N/A

8.6 Follow-up of subjects withdrawn from treatment

N/A

8.7 Premature termination of the study

N/A

9. SAFETY REPORTING

Temporary halt for reasons of subject safety

In accordance to section 10, subsection 4 of the WMO, the sponsor will suspend the study if there is sufficient ground that continuation of the study will jeopardise subject health or safety. The sponsor will notify the accredited METC without undue delay of a temporary halt including the reason for such an action. The study will be suspended pending a further positive decision by the accredited METC. The investigator will take care that all subjects are kept informed.

9.2 (Serious) Adverse events

9.2.1 Adverse events (AEs)

Adverse events are defined as any undesirable experience occurring to a subject during the study that is related to wearing the GENEActiv or Axivity AX3 Logging tri-axial accelerometers.

Wearing accelerometers may cause mild skin redness or irritation due to prolonged contact with the device. This is considered an expected adverse event of mild severity. Participants will be instructed to monitor their skin daily and only report signs of persisting irritation to the researcher. Mitigation strategies include the use of breathable hypoallergenic straps, participant instruction on proper device use, and how to treat the affected area with moisturising skin cream. Only severe or persistent irritation will be reported as an AE.

9.2.2 Serious adverse events (SAEs)

A serious adverse event is any untoward medical occurrence or effect that

- results in death;
- is life threatening (at the time of the event);
- requires hospitalisation or prolongation of existing inpatients' hospitalisation;
- results in persistent or significant disability or incapacity;
- is a congenital anomaly or birth defect; or

- any other important medical event that did not result in any of the outcomes listed above due to medical or surgical intervention but could have been based upon appropriate judgement by the investigator.

Hospital admissions, that occur between the day of signing the Informed Consent and the day the participant starts wearing the accelerometers, will not be considered an SAE.

Excessive, outside normally expected range complications will be considered as SAE as determined by the patient's primary orthopaedic surgeon. The investigator will report all SAEs to the sponsor without undue delay after obtaining knowledge of the events, except for the following SAEs. The sponsor will report the SAEs through the web portal ToetsingOnline to the accredited METC that approved the protocol, within even days of first knowledge for SAEs that result in death or are life threatening followed by a period of maximum of eight days to complete the initial preliminary report. All other SAEs will be reported within a period of maximum 15 days after the sponsor has first knowledge of the serious adverse events.

9.3. Follow-up of adverse events

All AEs will be followed until they have abated, or until a stable situation has been reached. Depending on the event, follow up may require additional tests or medical procedures as indicated, and/or referral to the general physician or a medical specialist. SAEs need to be reported till end of study within the Netherlands, as defined in the protocol.

9.4 Data Safety Monitoring Board (DSMB) / Safety Committee

N/A

10. STATISTICAL ANALYSIS

10.1 Primary study parameter(s)

Following the devices' return to the researcher, the recorded data will be downloaded and stored securely in a dedicated study folder on Rijnstate's digital network. The raw triaxial wrist and thigh acceleration data will be auto-calibrated to local gravitational acceleration (in g) and then converted to a Vector Magnitude (VM). VM, or Euclidean Norm, can be interpreted as the magnitude of acceleration the device was subjected to at each measurement, including gravitational acceleration. Non-wear detection procedures will be applied, and any such non-wear periods will be excluded from these analyses. The acceleration signal will be summarised to a common time resolution of one observation per minute and subjected to prediction models

to calculate physical activity energy expenditure, time in moderate-to-vigorous physical activity, and step count.

Raw accelerometry data will be processed using the R-project for Statistical Computing and open-source packages (R Foundation for Statistical Computing, Vienna, Austria). Statistical analysis will be conducted using STATA/SE version 17 (StataCorp, College Station, TX, USA). For descriptive statistics, we will report medians (interquartile ranges) or means (standard deviations) for continuous variables and proportions for categorical variables. To examine face validity and the performance of each multi-level linear regression model, we will conduct ANOVA repeat measures analysis to calculate Pearson's coefficient and Root Mean Squared Error metrics. Differential bias will be assessed by age, sex, and BMI categories.

10.2 Secondary study parameter(s)

Descriptive analysis of participant demographics and outcomes will be conducted. Medians and interquartile ranges will be calculated for discrete data, such as scores from the questionnaires (IPAQ-SF, SQUASH, EQ-5D-5L, and OHS). These will be visualised through box plots. Mean and standard deviation will be calculated for continuous parameters.

To conduct aetiological analysis based on sample size, we will perform univariate and multivariate regression to assess for statistically significant confounders in relation to the questionnaire outcomes, such as PAEE and patient characteristics.

11. ETHICAL CONSIDERATIONS

11.1 Regulation statement

The study will be conducted according to the principles of the Declaration of Helsinki (Seoul, Korea, October 2008) and in accordance with the Dutch Medical Research Involving Human Subjects Act (WMO).

11.2 Recruitment and consent

Participants will be approached by their treating orthopedic surgeon using an introduction letter and a Patient Information Form (PIF) which includes the Informed Consent Form (IC, see Appendix E). One week after sending the PIF/IC, the coordinating researcher will contact the patient by phone to ask whether the patient has any questions about the study, and whether he/she is willing to participate. No pressure will be placed on any individual to participate; it will be made clear that participation is entirely voluntary and that participation can cease at any time. Participants who are will be asked to sign and date the Informed Consent form and return it to the researcher in a pre-paid envelope.

11.3 Benefits and risks assessment, group relatedness

Benefits

Participating in this study has no direct benefits for the participants, but it may provide participants some insight into their own physical activity.

Risks

Participants in this study will be asked to continuously wear a triaxial accelerometer for ten days and nights on their non-dominant wrist and for 48 hours on their thigh. In some instances, individuals may experience minor skin irritation or develop a localised rash from wearing the wrist strap. This is similar to cases where one starts to use a new (regular) watch or other wrist-worn device. Leaving the monitor off for one night should alleviate this. If the strap is damp, drying both the skin and strap can also reduce irritations. However, if the irritation persists, participants are asked to remove the monitor and return it to the researcher in the prepaid padded envelope. If the irritation does not resolve on its own, a small amount of moisturising skin cream (e.g. Sudocrem, Nivea Soft, Bepanthen Zalf) may be applied to the affected area. This can be obtained without prescription from a pharmacist. The same treatment approach is recommended if minor skin irritation or a localised rash arises from using 3M Tegaderm Film strips (3M, UK), which will be used to secure the Axivity AX3 accelerometers on participants' thighs.

11.4 Incentives

Participants will not receive any incentives for their participation.

12. ADMINISTRATIVE ASPECTS, MONITORING AND PUBLICATION

12.1 Handling and storage of data and documents

All data handling and storage will comply with the EU General Data Protection Regulation and the Dutch Act on Implementation of the General Data Protection Regulation (Dutch: Uitvoeringswet AVG). All data collected during this study will be managed according to the FAIR principles in order to enhance and improve Findability, Accessibility, Interoperability and Reuse of research data.

All patient data will be handled confidentially. Each subject will be given an identification code and only the investigators involved in this study will have access to the subject identification code list which can be used to link the data to the patient. The code list and all raw patient data will be stored in a designated research folder on Rijnstate’s local computer mainframe.

The Rijnstate coordinating investigator/project leader will collect the patient source data from the electronic patient records. These data comprise the participant's hospital identification number, age, gender, Body Mass Index (BMI), the presence and severity of any cardiovascular, pulmonary or neuromuscular diagnoses, and the use of medications for these diagnoses. After full data collection, data will be transferred to STATA/SE version 17 (StataCorp, College Station, TX, USA). In this spreadsheet the participant data will be non-identifiable/anonymous. All accelerometer and patient-related (questionnaire) data will be coded and securely shared with the UK investigators via Surf Filesender (https://www.surf.nl/en/services/surffilesender). All data collected during this study will be kept under secure conditions at Rijnstate Hospital for 15 years after the research has ended and then it will be destroyed. Any information collected will be treated as confidential and used only in this study unless otherwise specified. All source data relating to consented study participants will be stored and processed in line with Rijnstate Hospital requirements. All source data held in paper form (Informed Consents) will be scanned and securely stored as soon as possible after the participant has signed it. Paper copies will be stored in the secured research lockable cabinet at the department of Orthopaedics of Rijnstate.

Before the study commences, the UK partner will sign a Data Transfer Agreement (Stichting Topklinische Ziekenhuizen template 'Beschikbaarstelling persoonsgegevens/versie maart 2021') with Stichting Rijnstate Ziekenhuis.

Privacy of the participants

Both the GENEActiv triaxial accelerometer and Axivity AX3 triaxial accelerometer do not store any personal identifiable data. A code number on each monitor is matched with a participant ID number. The key to this code is known by the research team only. The participants' personal details are stored separately. Other security mechanisms are also used to protect the participants' privacy. For example, both types of accelerometer do not have GPS and do not measure the location of where the participant is. The accelerometers are only measuring body movement i.e. whether it moves up/down, forward/back and side-to-side. Once the movement data is uploaded, only the research team will be able to match the movement data to other patient information.

12.2 Monitoring and Quality Assurance

Monitoring of this study will take place during the total study duration according to guidelines set out by the Samenwerkende Topklinische Ziekenhuizen (STZ) and as described in Standard Operating Procedure 'STZ SOP VC12 Monitoringplan' (STZ version 21-02-2019; Rijnstate version 8-5-2019). Monitoring will be performed by Rijnstate's local Research Ethics Office.

12.3 Amendments

Amendments are changes made to the research after a favourable opinion by the accredited METC has been given. All amendments will be notified to the METC that gave a favourable opinion. Non-substantial amendments will not be notified to the accredited METC and the competent authority, but will be recorded and filed by the sponsor.

12.4 Annual progress report

The sponsor/investigator will submit a summary of the progress of the trial to the accredited METC once a year. Information will be provided on the date of inclusion of the first subject, numbers of subjects included and numbers of subjects that have completed the trial, serious adverse events/ serious adverse reactions, other problems, and amendments.

12.5 Temporary halt and (prematurely) end of study report

The investigator/sponsor will notify the accredited METC of the end of the study within a period of eight weeks. The end of the study is defined as the last patient's last visit.

The sponsor will notify the METC immediately of a temporary halt of the study, including the reason of such an action. In case the study is ended prematurely, the sponsor will notify the accredited METC within 15 days, including the reasons for the premature termination.

Within one year after the end of the study, the investigator/sponsor will submit a final study report with the results of the study, including any publications/abstracts of the study, to the credited METC.

12.6 Public disclosure and publication policy

This study will be prospectively registered in a public trial registry before the first patient is recruited. All data will be the property of Rijnstate. Publication will be the responsibility of the coordinating and principal investigators. It is planned to publish the results of this study in a peer-reviewed journal and to present results at national and international meetings. It will not be possible to identify any individuals from any publication or presentation.

13. STRUCTURED RISK ANALYSIS

According to the Dutch Federation of University Medical Centers, the risk in this study is negligible ("verwaarloosbaar risico") because there is only a small risk of minimal damage ("kleine kans op lichte schade"). Patients will be asked to wear an accelerometer on their wrist for ten days, and to simultaneously wear one accelerometer on their surgical thigh for 48 hours.

Both accelerometers collect physical activity data automatically. Additionally, participants will be asked to complete four paper questionnaires at home (duration: 15 minutes).

13.1 Potential issues of concern

N/A.

13.2 Synthesis

Participating in this study has no direct benefits for the participants. Participants who consent to participate will be asked to:

1. Complete 4 paper questionnaires (duration: 15 minutes).

2. Wear the GENEActiv tri-axial accelerometer on the wrist continuously for ten days and nights, and wear one Activity Ax3 Logging tri-axial accelerometers on the surgical thigh continuously for 48 hours. Wearing accelerometers is common, usually well tolerated and there are no documented risks of wearing in particular or physical activity monitors in general.

14. REFERENCES

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Appendix: Participant Information Form

(English translation; original form will be in Dutch)

2. Title of the Study:

Physical Activity in Patients After Resurfacing and Total Hip Arthroplasty: An Observational Follow-up Study 15 Years After Surgery.

3. Introduction

Dear Sir/Madam,

This information letter is to ask whether you would like to participate in medical-scientific research. Participation is voluntary.

You are receiving this letter because you participated in the sports hip and/or treadmill test study at Rijnstate approximately 15 years ago. This document explains the nature of the current study, what it entails for you, and the potential benefits and risks. Please review the information carefully before deciding whether you want to participate. If you decide to participate, you can complete the form included in Appendix B.

4. Questions?

You can make your decision based on the information in this letter. Additionally, we recommend that you:
- Ask the physician or researcher any questions you may have.
- Discuss the study with your partner, family, or friends.
- Read the information on www.rijksoverheid.nl/mensenonderzoek.

5. General Information

The Rijnstate Hospital Foundation has set up this study in collaboration with researchers from Imperial College London. In this document, we will refer to Rijnstate as the 'sponsor.' Researchers, including doctors and investigators, will conduct the study. The costs of the study are covered by the researchers at Imperial College London.

This study invites all participants who took part in the sports hip and/or treadmill test study approximately 15 years ago.

6. What is the purpose of the study?

This study aims to examine how much you move and how physically active you are. We will measure the energy you expend during movement, the intensity of your activities, and the number of steps you take per day. This will be done using two motion sensors ('accelerometers'). By collecting this information, we hope to better understand how much people move after receiving a total hip prosthesis or a resurfacing hip prosthesis.

7. Background of the Study

Hip osteoarthritis can cause significant pain, often leading to reduced movement. For many individuals, this is a reason to undergo hip replacement surgery.
Hip prostheses usually reduce pain, but little is known about how active people remain after

surgery. Staying active is important for recovery and overall health post-surgery.
By researching how much people move after hip replacement surgery, doctors can better understand patient needs. This can help improve treatment and rehabilitation programs and provide better support for a healthier lifestyle. Furthermore, comparing different types of hip prostheses, such as total hip prostheses and resurfacing prostheses, can help doctors and patients make better-informed decisions.

8. How is the study conducted?

The study will last a total of 10 days. Participants will wear two different motion sensors and complete questionnaires from home.

9. Potential Side Effects, Discomfort, or Risks

Some individuals may experience mild skin irritation from wearing the motion sensors. This can be managed by using a moisturizer or removing the sensor temporarily.

10. Benefits and Drawbacks of Participation

There is no direct benefit to participation, but it may provide insight into your movement patterns. Data collected will help improve understanding of post-surgical mobility.

11. Withdrawal from the Study

You may withdraw at any time without providing a reason. This will not affect your medical care at Rijnstate.

12. Data Handling and Privacy

Your data will be coded to protect your privacy. Some data will be securely transferred to Imperial College London for analysis.

13. Compensation

No financial compensation is provided for participation in this study.

14. Contact Information

For study-related inquiries:
Dr. J.L.C. van Susante, Orthopedic Surgeon (Email: JvanSusante@rijnstate.nl)

For complaints:
Contact the Rijnstate complaints officer at: klachtenbureau@rijnstate.nl

15. Thank you

Thank you for your time and consideration.

Appendix: Informed Consent Form for the Study "Physical Activity of Patients with a Total Hip Prosthesis or a Resurfacing Hip Prosthesis: An Observational Follow-up Study 15 Years After Surgery."
(English translation; original form will be in Dutch)

- I have read the information letter. I was given the opportunity to ask questions. My questions have been sufficiently answered. I had enough time to decide whether I wanted to participate.
- I understand that participation is voluntary. I also understand that I can withdraw from this study at any time or revoke my participation without having to provide an explanation.
- I give permission to the researcher to collect and use my data. The researchers will do this solely to answer the questions in the study.
- I agree that my research data will be stored at Rijnstate for a period of 15 years after this study.
- I am aware that my coded data will also be sent to the United Kingdom, where EU privacy regulations do not apply. However, this is essential for the study. The data will be shared in coded form, without my name being disclosed. I consent to this.
- I want to participate in this study.

Please check "Yes" or "No" in below:

I give permission for my data to be used for other scientific research on physical activity, as described in the information letter.

☐ Yes

☐ No

First and Last Name of Participant (in block letters): ……

Signature: ……..

Date: / / (DD / MMM / YYYY)

_____

Declaration by the Researcher:

I declare that I have fully informed this participant about the study.

If any new information arises during the study that could influence the participant's consent, I will inform the participant in a timely manner.

Name of Researcher (or their representative): ……

Signature: ……..

Date: / / (DD / MMM / YYYY)

The participant will receive a full information letter and a copy of the fully signed consent form.