Ethical Clearance Summary Document: Relationship Between Risk Factors and The Incidence of Hip Osteoarthritis in Jember District

Researchers Name:

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TYPE OF RESEARCH: OBSERVATIONAL RESEARCH

Please describe where the research will be conducted
Regional Hospital dr. Soebandi Jember and Jember Clinic Hospital., Jember, East Java, Indonesia, 68121

Are the researchers have any health problems that might seriously impact their health during the study
The researchers have no health problems that might affect the research.

Contact Person: If things happen that are not planned and have a serious impact on the researcher, provide your name and personal information that can connect interested parties to the researcher during the research.

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RISKS TO RESEARCH PARTICIPANTS AND RESEARCHERS

Mention the inclusion and exclusion criteria of participants so that the risks and benefits of research are shared fairly
This study aims to 1) determine the risk factors and occupational characteristics related to hip osteoarthritis in Jember District and 2) determine the relationship of risk factors to the incidence of hip osteoarthritis in Jember District. The inclusion and exclusion criteria are:

a) Inclusion Criteria of Case Samples
   - Patients at the orthopedic polyclinic at the Regional Hospital dr. Soebandi Jember and Jember Clinic Hospital has a hip osteoarthritis diagnosis based on clinical and radiological criteria.
   - Patients agree to participate in the study by giving verbal and written consent
b) Exclusion Criteria of Case Samples
   - Patients who have a history of trauma, such as ligament rupture and pelvic fracture
   - Patients with metabolic disorders such as hyperuricemia
   - Patients with congenital pelvic deformities

How long will each research participant be in the research, from providing information to final contact with the research team?
Research participants were interviewed 45 minutes from the time they gave their consent. They are offered the opportunity to be contacted again by the research team, who will share a summary of research findings about three (3) months after the research conclusion.

Describe all risks and burdens resulting from participating in the research, such as pain, discomfort, distress, harm, or lifestyle changes, including if the research involves prolonged or repeated testing and use of drugs, placebos, or another substance. Describe what steps will be taken to minimize risks and burdens as far as possible.
The research will not cause harm/disorder/discomfort/lifestyle changes to participants. Researchers may ask questions that may unintentionally cause stress or concern. Participants have been briefed on the subject area of the question to anticipate this issue and have the right to disclose such information based on their knowledge.

Please describe what action you would take in case of unexpected results or adverse effects from participating in the research.
If study participants (respondents) have questions regarding further information about this hip osteoarthritis research, they can refer to the information sheet containing the researcher's contact details. Researchers will try to give more information if needed.

Will the interview/questionnaire or group discussion cover topics that may be sensitive, embarrassing, or upsetting (e.g., sexual activity, drug use, criminal activity, etc.)? Could criminal or other disclosures requiring action could have occurred during the research?

The research will not investigate any potentially embarrassing or problematic areas associated with sexual activity or drug use. Researchers only asked about the name, gender, age, weight, height, address, occupation, history of lifting weights, work posture, length, and duration of work.

If yes, please describe the procedure to deal with this problem.
Participants will be briefed in writing and verbally about the research topics, including sensitive areas as described above. Participants will be given consent papers to indicate their participation. However, they will also be assured that the data collected will be treated appropriately, kept confidential, and in line with relevant regulations. Accordingly, all data collected will be stored by international law and ITE law, including but not limited to United Nations Universal Declaration

of Human Rights, The latest version of the Declaration of Helsinki, and Indonesia's relevant national data protection laws and other laws intended to protect human rights.

What are the potential benefits for research participants? Is the risk or benefit ratio reasonable? (The potential risk must be proportional to the expected benefit level)
participants will benefit from providing information and discussion opportunities regarding osteoarthritis in general and its prevention. Researchers also give multivitamins to research participants with a maximum price of IDR 50,000 ($ 3)

Are any interventions or procedures part of the routine care of research participants? (If yes, provide details and justification). For example, disruption of a child's school day or access to their education rights and curriculum.
Observational studies do not require any interventions or procedures that would interfere with the participants' routine care.

What are the potential risks to the researchers, including locally employed staff? What actions do you have to minimize this risk?
Observational research probably doesn't have a risk to the researchers because research is conducted online, so there is no direct contact between researchers and participants.

How and by whom will the records or samples be identified?
Participants will be selected according to a predetermined Hip Osteoarthritis, based on the doctor's diagnosis on the medical record. Researchers will contact participants online to ask for data on name, gender, age, weight, height, address, occupation, history of lifting weights, work posture, length of work, and duration of work. This data will be used to determine what risk factors affect hip osteoarthritis. The research results will be processed using a data processing application.

Is there a requirement that participants may be 'required' to participate - as in the case of students, prisoners, patients, or NGO beneficiaries
This research does not require participants (respondents) to be involved in this research because cooperation in research projects is entirely voluntary.

Has prior consent been obtained, or will it be brought to access personal information during the identification of participants?
This research needs to collect and process potentially sensitive personal information about participants. With the consent of the participants, the researchers will collect the data and record the identity of the participants. However, if participants prefer to remain anonymous, their wishes will be respected, and the researchers will assign a personal identification number to each individual. Other sensitive information, such as age or gender, that participants do not wish to disclose must be anonymized. Researchers ensure participants that their participation is entirely voluntary.

Will you obtain consent from research participants? (If 'yes,' provide details. If you do not plan to seek consent, explain why; you must demonstrate that research would not be possible to conduct if participants disagreed on consent).
Participants will be asked in a form to indicate their consent that the data collected from them will: a) be used for research purposes only; b) be available in print publications and through online

open-access journals. They are free to ask that their relevant data be anonymized. Before or during the study, participants were free to withdraw their participation without giving reasons for their decision.

PERSONAL DATA AND CONFIDENTIALITY

What data do you need to collect (for example: is any minimum data required for research purposes)?
I need data from participants, especially those relating to name, gender, age, weight, height, address, occupation, history of lifting weights, work posture, length of work, and duration of work. I also need scientific data from national and international medical journals, which may be available online. It will be an observational study with a total sampling method with no minimum data required.

Does it violate any personal rights?
The collection of data does not violate any personal rights.

Have you included a privacy notice in the participant information sheet?
Yes, the researchers provide a privacy notice in the participant information sheet. Participants will also be briefed on privacy questions.

What will happen if the data is leaked?
Research is designed with safety systems to ensure that data will not be leaked. For example, it will be stored on an encrypted, field-protected hard drive and password-protected servers. Participants were notified of the possibility of a data breach; strict action will be taken to ensure that such a breach does not occur.

What actions have been taken to reduce the risk to participants?
As indicated in the section above on 'Recruitment and Participation,' the researchers will try to reduce the risk to individuals in the following way: the researchers will provide a personal identification number for each individual in which the participant prefers to remain anonymous. Other sensitive information, such as age or gender, that participants do not wish to disclose must be anonymized.

How do you plan to store, access, and process the data?
All data collected and stored will comply with relevant national and international laws. Unprocessed data may be retained due to obligations to make it available for audit or publication in a journal. Data destruction is done after permission from the research ethics committee.

Who will have access to the participant's data during the research? Will there be third-party involvement in processing the data?
Only researchers will have access to the data; no third parties will have access to the data.

Will the data be transferred outside Indonesia?
NO. The data will be fully used for research in Indonesia. However, the research results can be published by publishers from outside Indonesia.

How will you ensure the confidentiality of personal data? (example: data anonymization) Can you completely anonymize the data and still get the same results? If it is planned to keep participants identifiable, give reasons. Participants must not be exposed to harm as they remain identifiable, which is still part of their informed consent.
The data will be completely anonymized.

What will you do with the data when you're done with it? How long will personal information be stored or accessed after the research ends? (If more than 12 months, please justify)
Data will be stored for 24 months to make it accessible to other researchers who may wish to expand on the research by applying their data or insights.

REPORTING AND DISSEMINATION

How would you like to report and disseminate the results of the study? Please provide your reason if you do not plan to write or disseminate the results.
Researchers plan to publish articles in international journals.

Will you inform participants about the results? (Please provide details on how and when you will inform participants) Efforts should be made to notify participants and others who may get benefit from these findings.
The research results can be accessed by participants, organizations, or institutions that focus on research if published in a journal.

I have read and understood the contents of the ethical clearance above. All the information contained does not conflict with the fundamental rights of the interviewer, the people being interviewed and all parties involved during the field research activities.

Suppose in the future there is a violation of one or several provisions/information contained in the ethical clearance. In that case, I am willing to be questioned for the good of the parties involved during the research.

Jember, 2nd February 2022
Best regards,

Ika Rahmawati Sutejo
Chief of Researchers