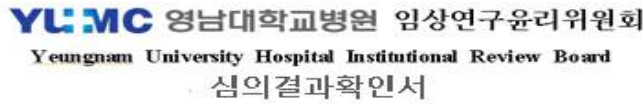


IRB Review and Approval Confirmation Form



Trial Details

IRB Serial No.

YUMC IRB 2024-10-018

Name and Address of IRB :

Institutional Review Board, Yeungnam University Hospital 170, Hyeonchung-ro, Nam-gu, Daegu, 42415 Korea

Protocol No.

NA

Protocol version

NA

Protocol Title

Patterns of recovery after arthroscopic repair of the rotator cuff over a 2-year follow-up period: are they similar regardless of the size of the tear?

Principal Investigator

Sam Guk Park / Orthopedic Surgery

Funding Source

NA

Classification

☐ Embryo Production ☐ Embryo Research ☐ DNA Test ☐ Genetic Study
☐ DNA Bank ☐ Gene Therapy ☐ Somatic Cell ☐ Embryo Clones

☒ Case-series study using medical records ☐ Surveys ☐ observational study
☐ Research using biological samples (☐ Stored Samples ☐ Collecting new samples)

☐ Drugs ☐ Devices ☐ Procedures ☒ Others

Product

NA

Phase

☐ Phase I ☐ Phase II ☐ Phase III ☐ Phase IV ☐ PMS ☐ Bioequivalence

☒ Others : Retrospective study

List of Documents reviewed / approved by IRB

Submitted documents

☒ New protocol ☐ Amendment ☐ Suspended or Early-closed Report
☐ Supplement (Conditional Approval) ☐ Interim Report
☐ Continued Review on Approved Protocol ☐ Supplement (Re-review)
☐ Final Report ☐ Subject Wanted Ad ☐ Close-out Report ☐ Others:

Results of Review

☒ Approval ☐ Conditional Approval ☐ Supplement (Conditional Approval) ☐ Rejection
☐ Supplement(Re-review) ☐ Suspension or Reservation of Approved Clinical Trial

Date of Approval

28-Oct-2024

Continuing Review

☐ 3 Month ☐ 6 Month ☒ 1 Year ☐ Others

Review Items & Versions Information

(Appendix) Protocol
(Appendix) Exemption of Consent reason letter
(Appendix) Protocol summary
(Appendix) Case Report Form CRF
(Appendix) Declaration Form for Conflicts of Interests
(Appendix) Curriculum Vitae of Principal Investigator & GCP Certificate

Review Opinion

☒ IRB committee reviewed an approved submitted protocol under the standards and regulations of ICH-GCP, KGCP and IRB committee of Yeungnam University Hospital.

Yeungnam University Hospital
Institutional Review Board Chairman



Note :

1. IRB complies with the standards and regulations of ICH-GCP, KGCP and with the applicable regulatory requirement(s).
2. Investigators are authorized to proceed the study with an approval of IRB.
3. In carrying out research, investigators should advance the study with an originally proposed protocol, consent form and CRF.
4. Principal Investigator shall report to IRB immediately in case of Serious Adverse Event. Also, immediate actions include an occurrence of new information which might harm research applicants.
5. The researcher should cooperate and submit research-related documents under the request of IRB. Also, investigators should follow the primary protocol as proposed except the circumstances which can endanger the participants enrolled in the research.
6. At the request of the committee, Report related to progress of research should be submitted.
7. Before using Target Recruitment Ad, Ad should be approved by committee.
8. Except compulsion or undue influence, Investigator should perform a well-informed consent process and give enough opportunities for Potential target to consider participating in research.
9. When you have an objection to committee's decision, you can submit a statement of protest.
10. IRB committee reviewed an approved submitted protocol under the standards and regulations of ICH-GCP, KGCP and IRB committee of Yeungnam University Hospital.
11. IRB committee excluded members who has conflict of interest from the review.
12. Institutional Review Board, Yeungnam University Hospital, 170, Hyeonchung-ro, Nam-gu, Daegu, 42415 Korea
Tel: 053-624-8352, Fax: 053-624-8356