



Chung-Ang University Hospital Institutional Review Board (IRB)

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Official Report of IRB Review

This letter is to inform you of the results of IRB review.

Reason for Request of review	☒ Initial Review ☐ Modifications or changes to the Protocol ☐ Unanticipated Problems or Non-Compliance ☐ Continuing Review ☐ Final Report ☐ Others		
Title of Study	Comparison between Single plate fixation with medial cannulated cancellous screw(CCS) fixation and double plate fixation for transcondylar fracture of distal humerus		
	Protocol No.		Version No. 1.0
IRB No	2506-026-19581	Date of Review	03. Jul. 2025
Investigator	Jae-Sung Lee M.D. Ph.D	Department	Department of Orthopaedic Surgery
Study Agent(s)	Generic Names(s)		Brand Name(s)
Phase	☐ Phase I ☐ Phase II ☐ Phase III ☐ Phase IV ☐ PMS ☐ Bioequivalence ☒ others		
Proposed Period of Study	03. Jul. 2025 ~ 02. Jul. 2026		
Sponsor			
Result of Review	☒ Approved ☐ Approved with Condition ☐ Modifications Requires ☐ Disapproved		
Continuing review report interval	1 year		
Reviewer's comments	The initial document was approved.		

This is to certify that the information contained herein is true and correct as reflected in the records of the Chung-Ang University Hospital IRB. We certify that Chung-Ang University Hospital IRB is in full compliance with Good Clinical Practice as defined under the Korea Food and Drug Administration (KFDA) regulations and functions in accordance with the ICH GCP Guidelines (CPMP/ICH/135/95) and the Korean national ethics requirements.

Jeong-Kyu Lee
Chairperson

03-Jul-25
Date

