

SNUBH IRB

SEOUL NATIONAL UNIVERSITY BUNDANG HOSPITAL INSTITUTIONAL REVIEW BOARD

TEL: 82-31-787-8801~6

FAX: 82-31-787-8869

ADDRESS: 82, GUMI-RO 173BEON-GIL BUNDANG-GU, SEONGNAM-SI, GYEONGGI-DO, 13620, KOREA

SNUH

분당서울대학교병원

IRB Decision

Notification

Document

The followings were Reviewed:

IRB No : B-1610/368-304

Report No. : E3-2018-1319

Research Project Title : A comparative analysis of clinical application and effect between plastic cast and open cast

Protocol No : N/A / **Version No :** 5.1

Investigator: Moon Seok Park, M.D., Ph.D.

Sponsor: N/A / **Funding Source:** openM inc.

Protocol Approval Date: 2016-12-06 / **Approval Period :** 12months / **Approval effective period:** ~2019-12-05

Receipt date: 2019-01-18

Review date: 2019-01-18

Risk of the study : Minimal Risk

Review Type: Expedited Review

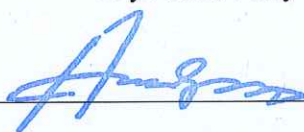
Review Item: Application for Annual Continuation Review

Review list: Application for Annual Continuation Review

Review Result: APPROVAL

All conditions of approval previously established by SNUBH IRB for this research project continue to apply.

If you have any questions, contact SNUBH IRB at 82-31-787-8801~6



Chairperson: Prof. Hak Chul Jang, M.D., Ph.D

2020. 03. 31

Date

This is to certify that the information contained herein is true and correct as reflected in the records of the SNUBH Institutional Review Board (SNUBH IRB).

WE CERTIFY THAT SNUBH IRB IS IN FULL COMPLIANCE WITH GOOD CLINICAL PRACTICES AS DEFINED UNDER THE KOREA FOOD AND DRUG ADMINISTRATION (KFDA) REGULATIONS AND THE INTERNATIONAL CONFERENCE ON HARMONISATION (ICH) GUIDELINES.

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All investigators performing SNUBH IRB approved projects must comply with the followings:

1. Enrollment of participated subjects before the IRB approval of protocol/protocol amendment is forbidden.
2. To conduct the study according to the approved protocol. To conduct the study differently from the original protocol is forbidden.
3. To use the approved Informed Consent Form.
4. The informed consent process shall be conducted based on sufficient explanation under no coercion or unfair influence, and a potential subject shall be provided with sufficient opportunity to consider the study participation.
5. Except for the unavoidable cases to protect subjects during the study conduct, any amendment of the study shall be implemented after getting the prior approval of the Board, and any amendment taken in an emergency situation for protection of subjects shall be immediately reported to the Board.
6. In case the study should be conducted differently from the original protocol since the immediate risk factor occurring to subjects should be eliminated, the amendment item that may increase risk factors occurring to subjects or have serious effects of the study conduct, items on the unexpected serious adverse drug reaction, or items on new information that may have negative effects on subjects' safety or study conduct shall be promptly reported to the Board.
7. The subject recruitment advertisement approved by the Board shall be used.
8. The Board approval period may not exceed one year. In case of intending to continue the study for more than one year, you are required to submit an annual continuation report, submit a report on the study progress in line with the interim reporting cycle as requested by the Board.
9. In case the IRB review decision is not an 'Approval', written response for IRB decision result shall be submitted within six months since the IRB review date.
10. In the case of a decision by the Board to disapprove, you may have the opportunity to submit an appeal in writing. However, you should not file an appeal 2 times in a row with the same reason.
11. When completing the research, Study completion report and Study result report shall be submitted.
12. You shall comply with Bioethics and Safety Act, Pharmaceutical Affairs Act/Medical Device Affairs Act as defined under the Ministry of Food and Drug Safety (MFDS) regulations, the International Conference on Harmonization (ICH) guidelines and the Declaration of Helsinki.
13. According to the Declaration of Helsinki, all clinical studies shall be disclosed in the database that allows public access(primary registry) prior to the first subject enrollment; for example, you may use <http://register.clinicaltrials.gov>. For details, please refer to the IRB website.
14. The internal audit or inspection from the regulatory agency for the approved study could be conducted. Investigator shall cooperate in helping this to carry out, when requested for reading of study document(including electronic document) by internal auditor or monitor from sponsor, or inspector from regulatory agency.

Korea FDA regulations require that the SNUBH IRB conduct review of approved research. You will receive Continuing Review Report forms from the SNUBH IRB. These reports must be returned even though your study may not have started.

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