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Appendix**Patient's consent form**

Title of the study: Combination of InnoSEAL plus TR band compared to TR Band alone for Radial Artery Outcomes in patients undergoing transradial coronary intervention (InnoSEAL – II)	
ERC Ref No: IORG 000 _____	Sponsor: InnoTherapy Inc. S. Korea
Principal investigator: Dr Asad Z Pathan Co-Investigators: Dr Saba Aijaz, Dr Sana Sheikh	Organization: Tabba Heart Institute, Karachi
Patient's name: _____	MR No: _____

PURPOSE OF THE STUDY

This study will be conducted in Tabba Heart Institute in which patients who undergo trans-radial coronary procedures will be randomized within few minutes after the procedure to either Catechol conjugated chitosan based pad plus TRBand or TRBand alone. The main purpose of this study is to compare the effect of InnoSEAL plus TR band or TR band alone on subsequent radial artery outcomes (Acute radial artery blockage and/or significant bleeding) after transradial intervention and to compare the difference in time needed to stop the bleeding from radial artery, time to termination of radial artery monitoring, patient's discharge and patient's discomfort between InnoSEAL plus TR band versus TRBand alone.

PROCEDURES

All adult patients coming to Coronary Catheterization Laboratory, Tabba Heart Institute (THI) for elective and urgent Trans-radial diagnostic catheterization and percutaneous coronary interventions will be invited to participate in the study. Those patients who consent to participate will get assigned to either TR band alone or in InnoSEAL plus TR band arm. TR band is a tight band like device which is routinely used in THI to stop bleeding from the cannula site at your wrist after the radial coronary procedure is completed. This band remains in place for few hours and is removed once radial bleeding is stopped. If you are assigned to InnoSEAL plus TR band arm, then an additional square patch which contains a chemical that helps in blood clotting will be applied to your wrist before the TR band. This patch and band remains in place for few hours and is removed once radial bleeding is stopped. Routine care after the bleeding stops is same for both the treatment arms. Pulse in your arm will be checked multiple times during this time. An ultrasound of our wrist may be performed to further confirm blood flow at the site of cannula.

The treatment you get assigned to will be totally based on chance and is pre-decided by a computer program. Our research coordinator has no control to allocate you to any treatment according to her or your choice.

RISKS OR DISCOMFORT

There are no adverse effects of this study. It will only take your valuable time which can cause inconvenience to you. We apologize for this inconvenience in advance.

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POSSIBLE BENEFITS

The possible benefits might include early removal of the TR band, which may lead to early discharge if you are planned same day discharge by your treating cardiologist. Also since the band and/ or InnoSEAL is applied for a lesser duration, there may be less discomfort in your hand related to hemostasis procedure.

FINANCIAL CONSIDERATIONS

No financial compensation will be provided to any of the study participants.

AVAILABLE MEDICAL TREATMENT FOR ADVERSE EXPERIENCES

Since you are our study participant, we will assist you in directing you to your correct care provider if any unrelated medical issue arises during the course of our study. Additionally, your participation in this study will not affect the care that you will continue to receive in THI.

CONFIDENTIALITY

Your identity will be kept confidential. Special measures will be taken to protect your identity and personal information. You will be given a unique identifier (code). Your data will be kept in lock and key and will only be accessible by the research team. In the electronic system one of the personal data will be entered and you will only be identified by a unique code. The results of the study will only be published for scientific purposes and your name or any identifiable references to you will not be included. The results will not be shared with anyone. Only the combined results will be shared in scientific meeting and journals.

WITHDRAWAL OF CONSENT

You have full authority to participate in the study or refuse to participate in it. You also have right to leave study anytime without any reason. Your decision to participate or refuse to participate will not affect the course of your treatment at THI at this time and even in the future.

AVAILABLE SOURCES OF INFORMATION

If you have any questions regarding this study please call at this number.

Dr. Saba Aijaz, Dr Sana Sheikh

Department of Cardiology. Tabba Heart Institute, Karachi. Pakistan

Phone: 021 36811842-50 (ext: 1372)

E-mail: saba.ajiaz@tabbaheart.org

AUTHORIZATION

I have read and understood this consent form, and I volunteer to participate in this research study. I understand that I will receive a copy of this form. I voluntarily choose to participate, but I understand that my consent does not take away any legal rights in the case of negligence or other legal fault of anyone who is involved in this study.

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Participant's Name: _____

Date: _____

Participant's Signature or thumb impression:

Signature of witness (use for non-literate patient)

Principal Investigator's/Co-PI's Signature:

Date: _____

Name/ Signature of Person Obtaining Consent:

Date: _____

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