Electronic Case Report Form

PROTOCOL	2021년 7월 교육실습
STUDY TITLE	2021년 7월 교육실습 (이송영)

SITE	-
책임 연구자	-
CRF Version	1.00
CRF Effective	-
스크리닝 번호	-
배정 번호	-
이니셜	-

	Enrollment	V1	V2	V3	V4	V5	UV1	All
Enrollment	☐							
Visit		☐	☐	☐	☐	☐	☐	
Demographics		☐						
Medical History		☐						
Vital Signs		☐	☐	☐	☐	☐	☐	
Local Laboratory Test		☐	☐				☐	
Pregnancy Test		☐	☐	☐				
Inclusion/ Exclusion Criteria		☐						
Randomization			☐					
IP Prescription		☐	☐	☐	☐	☐		
Adverse Event								☐
Prior and Concomitant Medications								☐
Disposition								☐
Principal Investigator's Signature								☐

Enrollment	
Date of informed consent	EN.ICDTC (C10) _____
Screening No.	EN.SUBJID (C6) ____

Visit	
Visit date	SV.SVDTC (C10) _____
Reason for unscheduled visit	SV.SVUVREAS (N2) [1] ○ Adverse event [2] ○ Others → Specify below
Others, specify	SVUVRECO (C10) _____

Level	ID	Property	Visit	Type	Cycle No.	Value
QST	SVUVREAS		All	Exclude	All	Reason for unscheduled visit
QST	SVUVREAS		UV##	Include	All	Reason for unscheduled visit
QST	SVUVRECO		All	Exclude	All	Others, specify
QST	SVUVRECO		UV##	Include	All	Others, specify

Demographics	
Birth date	DM.BRTHDTC (C10) _____
Age	DM.AGE (N2) 만 _ Years
Sex	DM.SEX (N2) [1] ○ Male [2] ○ Female
Alcohol	DM.ALCOHOL (N2) [1] ○ Yes [2] ○ No

Medical History

ND	MY.MHND (N1) [1] ☐ ND

No	Medical history term	Ongoing	End date	Administration ofr medication
MH.SEQ (N2) 1	MH.MHTERM (C255) _____ _____ _____	MH.MHONGO (N2) [1] ○ Yes [2] ○ No	MH.MHENDTC (C10) _____	MH.MHCONTRT (N2) [1] ○ Yes [2] ○ No

Vital Signs	
ND	VS.VSND (N1) [1] ☐ ND
Height	VS.HEIGHT (N3) __ cm
Weight	VS.WEIGHT (N3.1) ___ kg
Systolic blood pressure	VS.SYSBP (N3) __ mmHg
Diastolic blood pressure	VS.DIABP (N3) __ mmHg
Pulse rate	VS.PULSE (N3) __ beats/min
Respiratory rate	VS.RESP (N3) __ breaths/min
Temperature	VS.TEMP (N2.1) ___ ℃
If there are any newly noted clinically significant abnormal result since the last Visit, please specify the details on the [Adverse Event] page	

PROTOCOL	PAGE	VISIT
2021년 7월 교육실습	Vital Signs	V1, V2, V3, V4, V5, UV##

Level	ID	Property	Visit	Type	Cycle No.	Value
QST	HEIGHT		All	Exclude	All	Height
QST	HEIGHT		V1	Include	All	Height

Local Laboratory Test

ND	LY.LBND (N1) [1] ☐ ND
Collection date	LY.LBDTC (C10) _____

*If there are any newly noted abnormal result since the last Visit, please specify the details on the [Adverse Event] page

Hematology

Test Name	Result	Normality	Clinically Significant
LB.LBTEST (C50) Erythrocytes	LB.LBORRES (N4.3) _____	LB.LBNOR (N2) [1] ○ Normal [2] ○ Abnormal	LB.LBCLSIG (N2) [1] ○ NCS [2] ○ CS
LB.LBTEST (C50) Hemoglobin	LB.LBORRES (N4.3) _____	LB.LBNOR (N2) [1] ○ Normal [2] ○ Abnormal	LB.LBCLSIG (N2) [1] ○ NCS [2] ○ CS
LB.LBTEST (C50) Hematocrit	LB.LBORRES (N4.3) _____	LB.LBNOR (N2) [1] ○ Normal [2] ○ Abnormal	LB.LBCLSIG (N2) [1] ○ NCS [2] ○ CS
LB.LBTEST (C50) Platelets	LB.LBORRES (N4.3) _____	LB.LBNOR (N2) [1] ○ Normal [2] ○ Abnormal	LB.LBCLSIG (N2) [1] ○ NCS [2] ○ CS
LB.LBTEST (C50) Leukocytes	LB.LBORRES (N4.3) _____	LB.LBNOR (N2) [1] ○ Normal [2] ○ Abnormal	LB.LBCLSIG (N2) [1] ○ NCS [2] ○ CS

Level	ID	Property	Visit	Type	Cycle No.	Value
QST	LBND		All	Include	All	ND
QST	LBDTC	COMMENT_APPEND	V1	Include	All	*If there are any clinically significant abnormal result, please specify the details on the [Adverse Event] page.

Pregnancy Test	
Was the pregnancy test performed?	PG.PGYN (N2) [1] ○ Yes [2] ○ No
Collection date	PG.PGDTC (C10) _____
Result	PG.PGORRES (N2) [1] ○ Positive [2] ○ Negative

Inclusion/Exclusion Criteria

Is the Subject eligible to participate in this clinical trial due to having satisfied all eligibility criteria?	IE.IEYN (N2) [1] ○ Yes [2] ○ No
Date of screening failure	IE.IEDTC (C10) _____
Reason of screening failure	IE.IEREAS (N2) [1] ○ Inclusion/Exclusion criteria not met → Specify below [2] ○ Subject's consent withdrawal [3] ○ Other → Specify below
Specify the reason of screening failure	IE.IEREASCO (C255) _____ _____ _____

Inclusion Criteria

1. Subject who is outpatient, either male or female, aged between 19 and 74 years old, inclusive.

2. Subject who has a Hemoglobin A1c (HbA1c) value between 7.0% and 9.0% at Visit 1.

3. Subject who has estimated glomerular filtration rate (eGFR) ≥ 45mL/min/1.73m^2.

4. Subject who has systolic blood pressure value at Visit 1.
a) Treated with antihypertensive drugs: systolic blood pressure < 180 mmHg
b) non-treated: 140mmHg ≤ systolic blood pressure < 180mmHg

Exclusion Criteria

1. Subject who has been diagnosed with type 1 diabetes mellitus.

2. Subject has aspartate aminotransferase (AST) or alanine aminotransferase (ALT) value exceeding 3 times of upper limit of the normal range, or bilirubin value exceeding 3 times of upper limit of the normal range at Visit 1.

3. Female subject of childbearing potential, who is not at least one year post-menopausalor is not surgically sterile, has positive for the pregnancy test (urine or serum) at Visit 1 or is not willing to use appropriate contraception during the study. Female subject is hoping to become pregnant or is currently pregnant or breast-feeding.

4. Subject who has a history of clinically significant acute artery disease(s) within 3 months prior to date of Visit 1.
5. Subject who has a history of heart failure or arrhythmia within 6 months prior to date of Visit 1.
6. Subject with secondary dyslipidemia or iatrogenic dyslipidemia at Visit 1.
7. Subject who has a history of malignant tumor

Randomization	
Is patient randomized?	RN.RNYN (N2) [1] ○ Yes [2] ○ No
AStrata	RN.RNSRATA (N2) [1] ○ 1 [2] ○ 2
Randomization No.	RN.RNNO (C10) _____

IP Prescription	
Is the IP prescribed?	IP.IPYN (N2) [1] ○ Yes [2] ○ No
Date of prescription [Click SAVE the bottom of the page to allocate IP]	IP.IPDTC (C10) _____
IP_CODE [Click SAVE the bottom of the page to allocate IP]	IP.IPCODE (C10) _____

Adverse Event

ND	AY.AEND (N1) [1] ☐ ND

Record all adverse events noted from Visit 1 to study completion.

Line Number	Adverse Event	Start date	Outcome	End date	SAE
		Severity	Relationship to study treatment	Action taken with study treatement	Other action taken
AE.SEQ (N2) 1	AE.AETERM (C255) _____ _____ _____	AE.AESTDTC (C10) _____	AE.AEOUT (N2) ____▼	AE.AEENDDTC (C10) _____	AE.AESER (N2) ____▼
		AE.AESEV (N2) ____▼	AE.AEREL (N2) ____▼	AE.AEACN (N2) ____▼	AE.AEACNOTH (N2) ____▼

AE.AEOUT (N2) Outcome	[1] Fatal , [2] Not recovered , [3] Recovered/Resolved , [4] Recovered/Resolved with sequelae , [5] Recovering/Resolving , [6] Unknown
AE.AESER (N2) SAE	[1] No , [2] Death , [3] Hospitalization , [4] Life threatening , [5] Congenital anomaly or birth defect , [6] Significant disability , [7] Other medically important event
AE.AESEV (N2) Severity	[1] Mild , [2] Moderate , [3] Severe
AE.AEREL (N2) Relationship to study treatment	[1] Not related , [2] Unlikely related , [3] Possibly related , [4] Related
AE.AEACN (N2) Action taken with study treatement	[1] Dose increased , [2] Dose not changed , [3] Dose reduced , [4] Drug interrupted , [5] Drug withdrawn , [6] Not applicable , [7] Unknown
AE.AEACNOTH (N2) Other action taken	[1] None , [2] Drug treatment , [3] Non-drug treatment , [4] Drug and non-drug treatment

Prior and Concomitant Medications

ND	CY.CMND (N1) [1] ☐ ND

Please record all medications within 4 weeks prior to Visit 1 except for IP.

Line Number	Medication or therapy	Total daily dose	Dose Unit	Route
	Start date	Ongoing	End date	Indication
SEQ (N2) 1	CM.CMTRT (C255)	CM.CMDOSTOT (N5.3)	CM.CMDOSU (C255)	CM.CMROUTE (C255)
	CM.CMSTDTC (C10)	CM.CMONGO (N1) [1] ☐	CM.CMENDTC (C10)	CM.CMINDC (N1) CM.CMINDCMH (C255) CM.CMINDCAE (C255) CM.CMINDCO (C255)

CM.CMINDC (N1) Indication	[1] Medical history , [2] Adverse event , [3] Other
CM.CMINDCMH (C255) Medical history	
CM.CMINDCAE (C255) Adverse event	

CM.CMINDCO (C255) Other	_____ _____ _____

Disposition	
What was the subject's status?	DS.DSDECOD (N2) [1] ○ Completed [2] ○ Withdrawal
What was the date of study completed/withdrawal ?	DS.DSDTC (C10) _____
Reason for withdrawal	DSREAS (N2) [1] ○ Failure to meet randomization criteria → Specify below [2] ○ Withdrawal by subject [3] ○ Lost to follow-up [4] ○ Adverse event [5] ○ Others → Specify below
Comment	DS.DSREASO (C255) _____ _____ _____

PROTOCOL	PAGE	VISIT
2021년 7월 교육실습	Principal Investigator's Signature	Principal Investigator's Signature

Principal Investigator's Signature	
Investigator's Signature	SN.SNNAME (C10)
Signature Date	SN.SNDTC (C30)