Effects of carrimycin on biomarkers of inflammation and immune function in tumor patients with sepsis: A multicenter double-blind randomized controlled trial

Case Report Form

Version number: V1.0

Version date: 20191022

Subject Screening Number: | __|__ | - | __|__|__ |

The subjects initials: | __|__|__|__ |

Centre for the study of name: The First Affiliated Hospital of Harbin Medical University

Principal Investigator: Jiangkai Yu

Protocol No.	Screening number	Name abbreviation	Screening Period （D-7~D0）
KLMS-2019001	|__|__|-|__|__|__|	|__|__|__|__|	

Screening Period

Visit date:|__|__|__|__|-|__|__|-|__|__|

Informed consent signed date:|__|__|__|__|-|__|__|-|__|__|

Demographic data			
Date of birth	|__|__|__|__|-|__|__|-|__|__|	gender	□1 男 □2 女
nationality	□1 The han nationality □2 Others_____		
height	|__|__|__|.|__| cm	weight	|__|__|__|.|__| kg

Medical history and complications			
Diagnosis Date of major diseases: □sepsis |__|__|__|__|-|__|__|-|__|__| Diagnosis time:□≤48h □>48h			
Does the subject have any other comorbidities?□0No □1Yes,if "yes" please record below			
Name of disease	Date of diagnosis	End date	Still present
	|_|_|_|_|/|_|_|/|_|_|	|_|_|_|_|/|_|_|/|_|_|	□1 Yes
	|_|_|_|_|/|_|_|/|_|_|	|_|_|_|_|/|_|_|/|_|_|	□1 Yes
	|_|_|_|_|/|_|_|/|_|_|	|_|_|_|_|/|_|_|/|_|_|	□1 Yes

Histological diagnosis
Clinical diagnosis:_____ Histological specimens collected date: |_|_|_|_|-|_|_|-|_|_| Date of diagnosis: |_|_|_|_|-|_|_|-|_|_| Diagnosis:_____

Protocol No.	Screening number	Name abbreviation	Screening Period （D-7~D0）
KLMS-2019001	|__|__|-|__|__|__|	|__|__|__|__|	

Other previous medical history			
Have you experienced or are experiencing related medical conditions? □0 NO		□1 Yes, please fill out the following form.	
Name of Disease	**Date of diagnosis**	**Is it currently ongoing?**	
		YES	**No, end date**
1.	|_|_|_|_|/|_|_|/|_|_|	□	|_|_|_|_|/|_|_|/|_|_|
2.	|_|_|_|_|/|_|_|/|_|_|	□	|_|_|_|_|/|_|_|/|_|_|
3.	|_|_|_|_|/|_|_|/|_|_|	□	|_|_|_|_|/|_|_|/|_|_|
4.	|_|_|_|_|/|_|_|/|_|_|	□	|_|_|_|_|/|_|_|/|_|_|
5.	|_|_|_|_|/|_|_|/|_|_|	□	|_|_|_|_|/|_|_|/|_|_|

The history of surgery		
Is there a history of surgery? □0 NO		□1 YES
Name of Operation	**Surgery start date**	**Surgery end date**
1.	|_|_|_|_|/|_|_|/|_|_|	|_|_|_|_|/|_|_|/|_|_|
2.	|_|_|_|_|/|_|_|/|_|_|	|_|_|_|_|/|_|_|/|_|_|
3.	|_|_|_|_|/|_|_|/|_|_|	|_|_|_|_|/|_|_|/|_|_|

History of antineoplastic therapy (nearly one month) □0 NO □1 YES					
Type of treatment	Name of treatment (including medication)/radiotherapy site	Usage and dosage	Start date	Still in use	End date
			|_|_|_|_|/|_|_|/|_|_|	□1	|_|_|_|_|/|_|_|/|_|_|
			|_|_|_|_|/|_|_|/|_|_|	□1	|_|_|_|_|/|_|_|/|_|_|
			|_|_|_|_|/|_|_|/|_|_|	□1	|_|_|_|_|/|_|_|/|_|_|
Treatment of type: 1 = chemotherapy;2= immunotherapy;3= radiation therapy;4= targeted therapy;5= interventional therapy;6= other					

Protocol No.	Screening number	Name abbreviation	Screening Period （D-7~D0）
KLMS-2019001	|__|__|-|__|__|__|	|__|__|__|__|	

Other medication history (other medication before signing informed consent) □0NO □1Yes

Name of medication (Generic name)	Reason for medication	A single dose	unit (1)	Frequency of administration (2)	Route of administration (3)	Start date	Does it last?	
							YES	NO → end date
							□	
							□	
							□	

(1) Units		(2) Frequency of administration		(3) Route of administration	
1= grams (g)	2= mg (mg)	1= 1 times a day (QD)	2= 2 times daily (BID)	1= Oral (PO)	2= Intravenous (IV)
3= milliliters (ml)	4= micrograms (μg)	3= 3 times a day (TID)	4= 4 times daily (QID)	3= Intramuscular injection (IM)	4= Subcutaneous (SC)
5= Others, please specify		5= 1 every other day (QOD)	6= If necessary (PRN)	5= Topical (TOP)	6= Inhalation (INH)
		7= other, please specify		7= other, please specify	

Vital Signs

Inspection date: | __|__|__|__ | -| __|__ | - | __|__ | □0 Did not check

Body temperature	|__|__| |__| ℃	Heart rate	|__|__|__| times/min
breathing	|__|__|times/min	Blood pressure	|__|__|__|/|__|__|__| mmHg (systolic/diastolic blood pressure)

Protocol No.	Screening number	Name abbreviation	Screening Period （D-7~D0）
KLMS-2019001	|__|__|-|__|__|__|	|__|__|__|__|	

SOFA score	
system	**score**
Respiratory system	□ 0 points □ 1 points □2 points □3 points □4 points
Clotting system	□ 0 points □ 1 points □2 points □3 points □4 points
The liver	□ 0 points □ 1 points □2 points □3 points □4 points
Cardiovascular System	□ 0 points □ 1 points □2 points □3 points □4 points
Central Nervous System	□ 0 points □ 1 points □2 points □3 points □4 points
kidney	□ 0 points □ 1 points □2 points □3 points □4 points
Total score	Automatically calculate |__|__| (EDC)

APACHE Ⅱ score	
project	**score**
A. Age	□0 points: ≤44 □2 points: 44-54 □3 points: 55-64 □5 points: 65-74 □6 points: ≥75
B. Severe organ system dysfunction or immune impairment	□5 points: Inoperable or after emergency surgery □2 points: After Non-surgical or elective surgery □0 points: None of the above conditions
GCS score	|__|__|points
C. the integral	|__|__|points (EDC automatic computing: integral = 15 - GCS)
D. physiological indexes	|__|__|points
APACHE Ⅱ score	|__|__| (EDC automatic computing: the score = A + B + C + D)

Protocol No.	Screening number	Name abbreviation	Screening Period （D-7~D0）
KLMS-2019001	|__|__|-|__|__|__|	|__|__|__|__|	

project	unit	results	Clinical significance determination 1 2 3 0	Note
Routine blood sampling date: |_|_|_|_|/|_|_|/|_|_| □ did not check				
Red blood cell count (RBC)	X 10^{12}/L		□1 □2 □3 □0	
Hemoglobin (HGB)	g/L		□1 □2 □3 □0	
White Blood cell count (WBC)	X 10^{9}/L		□1 □2 □3 □0	
Platelet count (PLT)	X 10^{9}/L		□1 □2 □3 □0	
Red Blood cell volume (HCT)	%		□1 □2 □3 □0	
Routine urine sampling date: |_|_|_|_|/|_|_|/|_|_| □ did not check				
Protein (PRO)	qualitative		□1 □2 □3 □0	
Urine white blood cells	A/uL		□1 □2 □3 □0	
Urine red blood cells	A/uL		□1 □2 □3 □0	
Blood biochemical sampling date: |_|_|_|_|/|_|_|/|_|_| □ did not check				
Alanine aminotransferase (ALT)	U/L		□1 □2 □3 □0	
Aspartic acid aminotransferase (AST)	U/L		□1 □2 □3 □0	
Total bilirubin (TBIL)	μmol/L		□1 □2 □3 □0	
Glucose (GLU)	mmol/L		□1 □2 □3 □0	
Blood creatinine (Cr)	μmol/L		□1 □2 □3 □0	
Urea nitrogen (BUN)/urea	mmol/L		□1 □2 □3 □0	
Immunology related inspection Sampling date: |_|_|_|_|/|_|_|/|_|_| □ did not check				
Creactive protein (CRP)	μ g/mL		□1 □2 □3 □0	
Procalcitonin (PCT)	ng/mL		□1 □2 □3 □0	
Human Leukocyte Surface Antigen -DR (HLA-DR)	qualitative		□1 □2 □3 □0	
IL6	pg/mL		□1 □2 □3 □0	
IL8	pg/mL		□1 □2 □3 □0	
IL10	pg/mL		□1 □2 □3 □0	
TNF-alpha	ng/mL		□1 □2 □3 □0	
PD-1	qualitative		□1 □2 □3 □0	
Expression of PD-1 in T	qualitative		□1 □2 □3 □0	

Protocol No.	Screening number	Name abbreviation	Screening Period （D-7~D0）
KLMS-2019001	|__|__|-|__|__|__|	|__|__|__|__|	

cells				
MDSC (myeloid inhibitory cells)	qualitative		□1 □2 □3 □0	
CD4+	A/ul		□1 □2 □3 □0	
CD8+	A/ul		□1 □2 □3 □0	

Protocol No.	Screening number	Name abbreviation	Screening Period （D-7~D0）
KLMS-2019001	|__|__|-|__|__|__|	|__|__|__|__|	

ECG				
Inspection date: |_|_|_|_|/|_|_|/|_|_|				□0 Did not check
Heart rate (bpm)	PR interval (ms)	QRS width (ms)	QT interval (ms)	QTC interval (ms)
| __|__|__ |	| __|__|__ |	| __|__|__ |	| __|__|__ |	| __|__|__ |
Check the result	□1Normal □2Abnormalities not clinically significant □3Abnormal clinical significance, please describe:			

Urine or blood pregnancy	
Have you had a urine or blood pregnancy test?	□0 NO □1YES □9 Not applicable
If not, reason not checked: _____	
Sampling method	□1A urine sample □2A blood sample
Date of examination	| __|__|__|__ | | __|__ | | __|__ |
Check the result	□1negative □2positive

Inclusion criteria (For patients enrolled in the study, all inclusion criteria must be selected as "Yes".)		
1) Informed consent has been signed by subject or legal representative;	□0 NO	□1YES
2) Age ≥18 and ≤75 years old;	□0 NO	□1YES
3) Meet Sepsis3.0 diagnostic criteria;	□0 NO	□1YES
4) SOFA rating: 2 to 13;	□0 NO	□1YES
5) Patients with malignant tumors (histological diagnoses).	□0 NO	□1YES

Exclusion criteria (For patients enrolled in the study, all exclusion criteria must be selected as "NO".)		
1) Make it clear that sepsis has been diagnosed for more than 48 hours;	□0 NO	□1YES

Protocol No.	Screening number	Name abbreviation	Screening Period （D-7~D0）
KLMS-2019001	|__|__|-|__|__|__|	|__|__|__|__|	

Exclusion criteria (For patients enrolled in the study, all exclusion criteria must be selected as "NO".)		
2) Concomitant with serious primary diseases affecting survival, including haematological disorders, haematological neoplasms, lymphomas and HIV;	□0 NO	□1YES
3) Liver or kidney single SOFA score ≥3 points of liver and kidney dysfunction;	□0 NO	□1 YES
4) Patients who have received tumor immunotherapy (such as PD□1/L1, CTLA4, etc.) within the last 1 month;	□0 NO	□1 YES
5) Organ transplant within the last 6 months;	□0 NO	□1 YES
6) Cannot be given by gastrointestinal diet, such as in patients with intestinal obstruction, etc		
7) Pregnant and lactating women, subjects (including male subjects) have pregnancy plans (including sperm and egg donation plans) or are unable to take effective contraceptive measures in the next 6 months;	□0 NO	□1 YES
8) Participated in any other clinical trials within the last 1 month;	□0 NO	□1 YES
9) Patients deemed unsuitable for inclusion by the investigators.	□0 NO	□1 YES

Randomization				
Was randomization successfully performed?				
□0NO, not random cause:				
□1YES,	Random date:	|_|_|_|_|/|_|_|/|_|_|	Random number:	|__|__|
	Drug release date	|_|_|_|_|/|_|_|/|_|_|	Drug number	|__|__|

Protocol No.	Screening number	Name abbreviation	Visit 1
KLMS-2019001	|__|__|-|__|__|__|	|__|__|__|__|	

Visit 1

Date of Visit
Does the subject continue with this visit?
□0NO, please fill in the "Early Exit" visit
□1YES, Date of visit: |_|_|_|_|/|_|_|/|_|_|

Vital signs			
Inspection date: |_|_|_|_|/|_|_|/|_|_|			□0 Did not check
Body temperature	|__|__|. |__| ℃	Heart rate	|__|__|__| times/min
breathing	|__|__| times/min	Blood pressure	|__|__|__|/|__|__|__|mmHg (systolic/diastolic blood pressure)

SOFA score	
system	**score**
Respiratory system	□ 0 points □ 1 points □2 points □3 points □4 points
Clotting system	□ 0 points □ 1 points □2 points □3 points □4 points
The liver	□ 0 points □ 1 points □2 points □3 points □4 points
Cardiovascular System	□ 0 points □ 1 points □2 points □3 points □4 points
Central Nervous System	□ 0 points □ 1 points □2 points □3 points □4 points
kidney	□ 0 points □ 1 points □2 points □3 points □4 points
Total score	Automatically calculate|__|__| (EDC)

Protocol No.	Screening number	Name abbreviation	Visit 1
KLMS-2019001	|__|__|-|__|__|__|	|__|__|__|__|	

APACHE Ⅱ score	
project	**score**
A. Age	□0 points: ≤44 □2 points: 44-54 □3 points: 55-64 □5 points: 65-74 □6 points: ≥75
B. Severe organ system dysfunction or immune impairment	□5 points: Inoperable or after emergency surgery □2 points: After Non-surgical or elective surgery □0 points: None of the above conditions
GCS score	|__|__|points
C. the integral	|__|__|points (EDC automatic computing: integral = 15 - GCS)
D. physiological indexes	|__|__|points
APACHE Ⅱ score	|__|__| (EDC automatic computing: the score = A + B + C + D)

Protocol No.	Screening number	Name abbreviation	Visit 1
KLMS-2019001	|__|__|-|__|__|__|	|__|__|__|__|	

project	unit	results	Clinical significance determination 1 2 3 0	Note
Routine blood sampling date: |_|_|_|_|/|_|_|/|_|_| □ did not check				
Red blood cell count (RBC)	X 10^{12}/L		□1 □2 □3 □0	
Hemoglobin (HGB)	g/L		□1 □2 □3 □0	
White Blood cell count (WBC)	X 10^{9}/L		□1 □2 □3 □0	
Platelet count (PLT)	X 10^{9}/L		□1 □2 □3 □0	
Red Blood cell volume (HCT)	%		□1 □2 □3 □0	
Routine urine sampling date: |_|_|_|_|/|_|_|/|_|_| □ did not check				
Protein (PRO)	qualitative		□1 □2 □3 □0	
Urine white blood cells	A/uL		□1 □2 □3 □0	
Urine red blood cells	A/uL		□1 □2 □3 □0	
Blood biochemical sampling date: |_|_|_|_|/|_|_|/|_|_| □ did not check				
Alanine aminotransferase (ALT)	U/L		□1 □2 □3 □0	
Aspartic acid aminotransferase (AST)	U/L		□1 □2 □3 □0	
Total bilirubin (TBIL)	μmol/L		□1 □2 □3 □0	
Glucose (GLU)	mmol/L		□1 □2 □3 □0	
Blood creatinine (Cr)	μmol/L		□1 □2 □3 □0	
Urea nitrogen (BUN)/urea	mmol/L		□1 □2 □3 □0	
Immunology related inspection Sampling date: |_|_|_|_|/|_|_|/|_|_| □ did not check				
Creactive protein (CRP)	μ g/mL		□1 □2 □3 □0	
Procalcitonin (PCT)	ng/mL		□1 □2 □3 □0	
Human Leukocyte Surface Antigen -DR (HLA-DR)	qualitative		□1 □2 □3 □0	
IL6	pg/mL		□1 □2 □3 □0	
IL8	pg/mL		□1 □2 □3 □0	
IL10	pg/mL		□1 □2 □3 □0	
TNF-alpha	ng/mL		□1 □2 □3 □0	
PD-1	qualitative		□1 □2 □3 □0	
Expression of PD-1 in T	qualitative		□1 □2 □3 □0	

Protocol No.	Screening number	Name abbreviation	Visit 1
KLMS-2019001	|__|__|-|__|__|__|	|__|__|__|__|	

cells				
MDSC (myeloid inhibitory cells)	qualitative		□1 □2 □3 □0	
CD4+	A/ul		□1 □2 □3 □0	
CD8+	A/ul		□1 □2 □3 □0	

Protocol No.	Screening number	Name abbreviation	Visit 1
KLMS-2019001	|__|__|-|__|__|__|	|__|__|__|__|	

ECG				
Inspection date: |_|_|_|_|/|_|_|/|_|_|				□0 Did not check
Heart rate (bpm)	PR interval (ms)	QRS width (ms)	QT interval (ms)	QTC interval (ms)
| __|__|__ |	| __|__|__ |	| __|__|__ |	| __|__|__ |	| __|__|__ |
Check the result	□1Normal □2Abnormalities not clinically significant □3Abnormal clinical significance, please describe:			

Protocol No.	Screening number	Name abbreviation	Visit 2
KLMS-2019001	|__|__|-|__|__|__|	|__|__|__|__|	

Visit 2

Date of Visit
Does the subject continue with this visit?
□0NO, please fill in the "Early Exit" visit
□1YES, Date of visit: |_|_|_|_|/|_|_|/|_|_|

Vital signs			
Inspection date: |_|_|_|_|/|_|_|/|_|_|			□0 Did not check
Body temperature	|__|__|. |__| ℃	Heart rate	|__|__|__| times/min
breathing	|__|__| times/min	Blood pressure	|__|__|__|/|__|__|__|mmHg (systolic/diastolic blood pressure)

SOFA score	
system	**score**
Respiratory system	□ 0 points □ 1 points □2 points □3 points □4 points
Clotting system	□ 0 points □ 1 points □2 points □3 points □4 points
The liver	□ 0 points □ 1 points □2 points □3 points □4 points
Cardiovascular System	□ 0 points □ 1 points □2 points □3 points □4 points
Central Nervous System	□ 0 points □ 1 points □2 points □3 points □4 points
kidney	□ 0 points □ 1 points □2 points □3 points □4 points
Total score	Automatically calculate|__|__| (EDC)

Protocol No.	Screening number	Name abbreviation	Visit 2
KLMS-2019001	|__|__|-|__|__|__|	|__|__|__|__|	

APACHE Ⅱ score	
project	**score**
A. Age	□0 points: ≤44 □2 points: 44-54 □3 points: 55-64 □5 points: 65-74 □6 points: ≥75
B. Severe organ system dysfunction or immune impairment	□5 points: Inoperable or after emergency surgery □2 points: After Non-surgical or elective surgery □0 points: None of the above conditions
GCS score	|__|__|points
C. the integral	|__|__|points (EDC automatic computing: integral = 15 - GCS)
D. physiological indexes	|__|__|points
APACHE Ⅱ score	|__|__| (EDC automatic computing: the score = A + B + C + D)

Protocol No.	Screening number	Name abbreviation	Visit 2
KLMS-2019001	|__|__|-|__|__|__|	|__|__|__|__|	

project	unit	results	Clinical significance determination 1 2 3 0	Note
Routine blood sampling date: |_|_|_|_|/|_|_|/|_|_| □ did not check				
Red blood cell count (RBC)	X 10^{12}/L		□1 □2 □3 □0	
Hemoglobin (HGB)	g/L		□1 □2 □3 □0	
White Blood cell count (WBC)	X 10^{9}/L		□1 □2 □3 □0	
Platelet count (PLT)	X 10^{9}/L		□1 □2 □3 □0	
Red Blood cell volume (HCT)	%		□1 □2 □3 □0	
Routine urine sampling date: |_|_|_|_|/|_|_|/|_|_| □ did not check				
Protein (PRO)	qualitative		□1 □2 □3 □0	
Urine white blood cells	A/uL		□1 □2 □3 □0	
Urine red blood cells	A/uL		□1 □2 □3 □0	
Blood biochemical sampling date: |_|_|_|_|/|_|_|/|_|_| □ did not check				
Alanine aminotransferase (ALT)	U/L		□1 □2 □3 □0	
Aspartic acid aminotransferase (AST)	U/L		□1 □2 □3 □0	
Total bilirubin (TBIL)	μmol/L		□1 □2 □3 □0	
Glucose (GLU)	mmol/L		□1 □2 □3 □0	
Blood creatinine (Cr)	μmol/L		□1 □2 □3 □0	
Urea nitrogen (BUN)/urea	mmol/L		□1 □2 □3 □0	
Immunology related inspection Sampling date: |_|_|_|_|/|_|_|/|_|_| □ did not check				
Creactive protein (CRP)	μ g/mL		□1 □2 □3 □0	
Procalcitonin (PCT)	ng/mL		□1 □2 □3 □0	
Human Leukocyte Surface Antigen -DR (HLA-DR)	qualitative		□1 □2 □3 □0	
IL6	pg/mL		□1 □2 □3 □0	
IL8	pg/mL		□1 □2 □3 □0	
IL10	pg/mL		□1 □2 □3 □0	
TNF-alpha	ng/mL		□1 □2 □3 □0	
PD-1	qualitative		□1 □2 □3 □0	
Expression of PD-1 in T	qualitative		□1 □2 □3 □0	

Protocol No.	Screening number	Name abbreviation	Visit 2
KLMS-2019001	|__|__|-|__|__|__|	|__|__|__|__|	

cells				
MDSC (myeloid inhibitory cells)	qualitative		□1 □2 □3 □0	
CD4+	A/ul		□1 □2 □3 □0	
CD8+	A/ul		□1 □2 □3 □0	

Protocol No.	Screening number	Name abbreviation	Visit 2
KLMS-2019001	|__|__|-|__|__|__|	|__|__|__|__|	

ECG				
Inspection date: |_|_|_|_|/|_|_|/|_|_|				□0 Did not check
Heart rate (bpm)	PR interval (ms)	QRS width (ms)	QT interval (ms)	QTC interval (ms)
| __|__|__ |	| __|__|__ |	| __|__|__ |	| __|__|__ |	| __|__|__ |
Check the result	□1Normal □2Abnormalities not clinically significant □3Abnormal clinical significance, please describe:			

Protocol No.	Screening number	Name abbreviation	Visit 3
KLMS-2019001	|__|__|-|__|__|__|	|__|__|__|__|	

Visit 3

Date of Visit
Does the subject continue with this visit?
□0NO, please fill in the "Early Exit" visit
□1YES, Date of visit: |_|_|_|_|/|_|_|/|_|_|

Vital signs			
Inspection date: |_|_|_|_|/|_|_|/|_|_|			□0 Did not check
Body temperature	|__|__|. |__| ℃	Heart rate	|__|__|__| times/min
breathing	|__|__| times/min	Blood pressure	|__|__|__|/|__|__|__|mmHg (systolic/diastolic blood pressure)

SOFA score	
system	**score**
Respiratory system	□ 0 points □ 1 points □2 points □3 points □4 points
Clotting system	□ 0 points □ 1 points □2 points □3 points □4 points
The liver	□ 0 points □ 1 points □2 points □3 points □4 points
Cardiovascular System	□ 0 points □ 1 points □2 points □3 points □4 points
Central Nervous System	□ 0 points □ 1 points □2 points □3 points □4 points
kidney	□ 0 points □ 1 points □2 points □3 points □4 points
Total score	Automatically calculate|__|__| (EDC)

Protocol No.	Screening number	Name abbreviation	Visit 3
KLMS-2019001	|__|__|-|__|__|__|	|__|__|__|__|	

APACHE Ⅱ score	
project	**score**
A. Age	□0 points: ≤44 □2 points: 44-54 □3 points: 55-64 □5 points: 65-74 □6 points: ≥75
B. Severe organ system dysfunction or immune impairment	□5 points: Inoperable or after emergency surgery □2 points: After Non-surgical or elective surgery □0 points: None of the above conditions
GCS score	|__|__|points
C. the integral	|__|__|points (EDC automatic computing: integral = 15 - GCS)
D. physiological indexes	|__|__|points
APACHE Ⅱ score	|__|__| (EDC automatic computing: the score = A + B + C + D)

Protocol No.	Screening number	Name abbreviation	Visit 3
KLMS-2019001	|__|__|-|__|__|__|	|__|__|__|__|	

project	unit	results	Clinical significance determination 1 2 3 0	Note
Routine blood sampling date: |_|_|_|_|/|_|_|/|_|_| □ did not check				
Red blood cell count (RBC)	X 10^{12}/L		□1 □2 □3 □0	
Hemoglobin (HGB)	g/L		□1 □2 □3 □0	
White Blood cell count (WBC)	X 10^{9}/L		□1 □2 □3 □0	
Platelet count (PLT)	X 10^{9}/L		□1 □2 □3 □0	
Red Blood cell volume (HCT)	%		□1 □2 □3 □0	
Routine urine sampling date: |_|_|_|_|/|_|_|/|_|_| □ did not check				
Protein (PRO)	qualitative		□1 □2 □3 □0	
Urine white blood cells	A/uL		□1 □2 □3 □0	
Urine red blood cells	A/uL		□1 □2 □3 □0	
Blood biochemical sampling date: |_|_|_|_|/|_|_|/|_|_| □ did not check				
Alanine aminotransferase (ALT)	U/L		□1 □2 □3 □0	
Aspartic acid aminotransferase (AST)	U/L		□1 □2 □3 □0	
Total bilirubin (TBIL)	μmol/L		□1 □2 □3 □0	
Glucose (GLU)	mmol/L		□1 □2 □3 □0	
Blood creatinine (Cr)	μmol/L		□1 □2 □3 □0	
Urea nitrogen (BUN)/urea	mmol/L		□1 □2 □3 □0	
Immunology related inspection Sampling date: |_|_|_|_|/|_|_|/|_|_| □ did not check				
Creactive protein (CRP)	μ g/mL		□1 □2 □3 □0	
Procalcitonin (PCT)	ng/mL		□1 □2 □3 □0	
Human Leukocyte Surface Antigen -DR (HLA-DR)	qualitative		□1 □2 □3 □0	
IL6	pg/mL		□1 □2 □3 □0	
IL8	pg/mL		□1 □2 □3 □0	
IL10	pg/mL		□1 □2 □3 □0	
TNF-alpha	ng/mL		□1 □2 □3 □0	
PD-1	qualitative		□1 □2 □3 □0	
Expression of PD-1 in T	qualitative		□1 □2 □3 □0	

Protocol No.	Screening number	Name abbreviation	Visit 3
KLMS-2019001	|__|__|-|__|__|__|	|__|__|__|__|	

cells				
MDSC (myeloid inhibitory cells)	qualitative		□1 □2 □3 □0	
CD4+	A/ul		□1 □2 □3 □0	
CD8+	A/ul		□1 □2 □3 □0	

Protocol No.	Screening number	Name abbreviation	Visit 3
KLMS-2019001	|__|__|-|__|__|__|	|__|__|__|__|	

ECG				
Inspection date: |_|_|_|_|/|_|_|/|_|_|				□0 Did not check
Heart rate (bpm)	PR interval (ms)	QRS width (ms)	QT interval (ms)	QTC interval (ms)
| __|__|__ |	| __|__|__ |	| __|__|__ |	| __|__|__ |	| __|__|__ |
Check the result	□1Normal □2Abnormalities not clinically significant □3Abnormal clinical significance, please describe:			

Protocol No.	Screening number	Name abbreviation	Visit 4
KLMS-2019001	|__|__|-|__|__|__|	|__|__|__|__|	

Visit 4

Date of Visit
Does the subject continue with this visit?
□0NO, please fill in the "Early Exit" visit
□1YES, Date of visit: |_|_|_|_|/|_|_|/|_|_|

Vital signs			
Inspection date: |_|_|_|_|/|_|_|/|_|_|			□0 Did not check
Body temperature	|__|__|. |__| ℃	Heart rate	|__|__|__| times/min
breathing	|__|__| times/min	Blood pressure	|__|__|__|/|__|__|__|mmHg (systolic/diastolic blood pressure)

SOFA score	
system	**score**
Respiratory system	□ 0 points □ 1 points □2 points □3 points □4 points
Clotting system	□ 0 points □ 1 points □2 points □3 points □4 points
The liver	□ 0 points □ 1 points □2 points □3 points □4 points
Cardiovascular System	□ 0 points □ 1 points □2 points □3 points □4 points
Central Nervous System	□ 0 points □ 1 points □2 points □3 points □4 points
kidney	□ 0 points □ 1 points □2 points □3 points □4 points
Total score	Automatically calculate|__|__| (EDC)

Protocol No.	Screening number	Name abbreviation	Visit 4
KLMS-2019001	|__|__|-|__|__|__|	|__|__|__|__|	

APACHE Ⅱ score	
project	**score**
A. Age	□0 points: ≤44 □2 points: 44-54 □3 points: 55-64 □5 points: 65-74 □6 points: ≥75
B. Severe organ system dysfunction or immune impairment	□5 points: Inoperable or after emergency surgery □2 points: After Non-surgical or elective surgery □0 points: None of the above conditions
GCS score	|__|__|points
C. the integral	|__|__|points (EDC automatic computing: integral = 15 - GCS)
D. physiological indexes	|__|__|points
APACHE Ⅱ score	|__|__| (EDC automatic computing: the score = A + B + C + D)

Protocol No.	Screening number	Name abbreviation	Visit 4
KLMS-2019001	|__|__|-|__|__|__|	|__|__|__|__|	

project	unit	results	Clinical significance determination 1 2 3 0	Note
Routine blood sampling date: |_|_|_|_|/|_|_|/|_|_| □ did not check				
Red blood cell count (RBC)	X 10^{12}/L		□1 □2 □3 □0	
Hemoglobin (HGB)	g/L		□1 □2 □3 □0	
White Blood cell count (WBC)	X 10^{9}/L		□1 □2 □3 □0	
Platelet count (PLT)	X 10^{9}/L		□1 □2 □3 □0	
Red Blood cell volume (HCT)	%		□1 □2 □3 □0	
Routine urine sampling date: |_|_|_|_|/|_|_|/|_|_| □ did not check				
Protein (PRO)	qualitative		□1 □2 □3 □0	
Urine white blood cells	A/uL		□1 □2 □3 □0	
Urine red blood cells	A/uL		□1 □2 □3 □0	
Blood biochemical sampling date: |_|_|_|_|/|_|_|/|_|_| □ did not check				
Alanine aminotransferase (ALT)	U/L		□1 □2 □3 □0	
Aspartic acid aminotransferase (AST)	U/L		□1 □2 □3 □0	
Total bilirubin (TBIL)	μmol/L		□1 □2 □3 □0	
Glucose (GLU)	mmol/L		□1 □2 □3 □0	
Blood creatinine (Cr)	μmol/L		□1 □2 □3 □0	
Urea nitrogen (BUN)/urea	mmol/L		□1 □2 □3 □0	
Immunology related inspection Sampling date: |_|_|_|_|/|_|_|/|_|_| □ did not check				
Creactive protein (CRP)	μ g/mL		□1 □2 □3 □0	
Procalcitonin (PCT)	ng/mL		□1 □2 □3 □0	
Human Leukocyte Surface Antigen -DR (HLA-DR)	qualitative		□1 □2 □3 □0	
IL6	pg/mL		□1 □2 □3 □0	
IL8	pg/mL		□1 □2 □3 □0	
IL10	pg/mL		□1 □2 □3 □0	
TNF-alpha	ng/mL		□1 □2 □3 □0	
PD-1	qualitative		□1 □2 □3 □0	
Expression of PD-1 in T	qualitative		□1 □2 □3 □0	

Protocol No.	Screening number	Name abbreviation	Visit 4
KLMS-2019001	|__|__|-|__|__|__|	|__|__|__|__|	

cells				
MDSC (myeloid inhibitory cells)	qualitative		□1 □2 □3 □0	
CD4+	A/ul		□1 □2 □3 □0	
CD8+	A/ul		□1 □2 □3 □0	

Protocol No.	Screening number	Name abbreviation	Visit 4
KLMS-2019001	|__|__|-|__|__|__|	|__|__|__|__|	

ECG				
Inspection date: |_|_|_|_|/|_|_|/|_|_|				□0 Did not check
Heart rate (bpm)	PR interval (ms)	QRS width (ms)	QT interval (ms)	QTC interval (ms)
| __|__|__ |	| __|__|__ |	| __|__|__ |	| __|__|__ |	| __|__|__ |
Check the result	□1Normal □2Abnormalities not clinically significant □3Abnormal clinical significance, please describe:			

Protocol No.	Screening number	Name abbreviation	Visit 5
KLMS-2019001	|__|__|-|__|__|__|	|__|__|__|__|	

Visit 5

Visit date: |_|_|_|_|/|_|_|/|_|_|

Supervision way	□1Telephone follow-up □2In-hospital follow-up
Subject status	□1Survival □2Death □3Lost to follow-up
Other follow-up contents	

Protocol No.	Screening number	Name abbreviation	Early exit
KLMS-2019001	|__|__|-|__|__|__|	|__|__|__|__|	

Early exit

Visit date: |_|_|_|_|/|_|_|/|_|_|

Vital signs			
Inspection date: |_|_|_|_|/|_|_|/|_|_|			□0 Did not check
Body temperature	|__|__|.| __ | ℃	Heart rate	| __|__|__ | times/min
breathing	|__|__| times/min	Blood pressure	|__|__|__|/|__|__|__| mmHg (systolic/diastolic blood pressure)

SOFA score	
system	**score**
Respiratory system	□ 0 points □ 1 points □2 points □3 points □4 points
Clotting system	□ 0 points □ 1 points □2 points □3 points □4 points
The liver	□ 0 points □ 1 points □2 points □3 points □4 points
Cardiovascular System	□ 0 points □ 1 points □2 points □3 points □4 points
Central Nervous System	□ 0 points □ 1 points □2 points □3 points □4 points
kidney	□ 0 points □ 1 points □2 points □3 points □4 points
Total score	Automatically calculate|__|__| (EDC)

Protocol No.	Screening number	Name abbreviation	Early exit
KLMS-2019001	|__|__|-|__|__|__|	|__|__|__|__|	

APACHE Ⅱ score	
project	**score**
A. Age	□0 points: ≤44 □2 points: 44-54 □3 points: 55-64 □5 points: 65-74 □6 points: ≥75
B. Severe organ system dysfunction or immune impairment	□5 points: Inoperable or after emergency surgery □2 points: After Non-surgical or elective surgery □0 points: None of the above conditions
GCS score	|__|__|points
C. the integral	|__|__|points (EDC automatic computing: integral = 15 - GCS)
D. physiological indexes	|__|__|points
APACHE Ⅱ score	|__|__| (EDC automatic computing: the score = A + B + C + D)

Protocol No.	Screening number	Name abbreviation	Early exit
KLMS-2019001	|__|__|-|__|__|__|	|__|__|__|__|	

project	unit	results	Clinical significance determination 1 2 3 0	Note
Routine blood sampling date: |_|_|_|_|/|_|_|/|_|_| □ did not check				
Red blood cell count (RBC)	X 10^{12}/L		□1 □2 □3 □0	
Hemoglobin (HGB)	g/L		□1 □2 □3 □0	
White Blood cell count (WBC)	X 10^{9}/L		□1 □2 □3 □0	
Platelet count (PLT)	X 10^{9}/L		□1 □2 □3 □0	
Red Blood cell volume (HCT)	%		□1 □2 □3 □0	
Routine urine sampling date: |_|_|_|_|/|_|_|/|_|_| □ did not check				
Protein (PRO)	qualitative		□1 □2 □3 □0	
Urine white blood cells	A/uL		□1 □2 □3 □0	
Urine red blood cells	A/uL		□1 □2 □3 □0	
Blood biochemical sampling date: |_|_|_|_|/|_|_|/|_|_| □ did not check				
Alanine aminotransferase (ALT)	U/L		□1 □2 □3 □0	
Aspartic acid aminotransferase (AST)	U/L		□1 □2 □3 □0	
Total bilirubin (TBIL)	μmol/L		□1 □2 □3 □0	
Glucose (GLU)	mmol/L		□1 □2 □3 □0	
Blood creatinine (Cr)	μmol/L		□1 □2 □3 □0	
Urea nitrogen (BUN)/urea	mmol/L		□1 □2 □3 □0	
Immunology related inspection Sampling date: |_|_|_|_|/|_|_|/|_|_| □ did not check				
Creactive protein (CRP)	μ g/mL		□1 □2 □3 □0	
Procalcitonin (PCT)	ng/mL		□1 □2 □3 □0	
Human Leukocyte Surface Antigen -DR (HLA-DR)	qualitative		□1 □2 □3 □0	
IL6	pg/mL		□1 □2 □3 □0	
IL8	pg/mL		□1 □2 □3 □0	
IL10	pg/mL		□1 □2 □3 □0	
TNF-alpha	ng/mL		□1 □2 □3 □0	
PD-1	qualitative		□1 □2 □3 □0	
Expression of PD-1 in T	qualitative		□1 □2 □3 □0	

cells				
MDSC (myeloid inhibitory cells)	qualitative		□1 □2 □3 □0	
CD4+	A/ul		□1 □2 □3 □0	
CD8+	A/ul		□1 □2 □3 □0	

Protocol No.	Screening number	Name abbreviation	Early exit
KLMS-2019001	|__|__|-|__|__|__|	|__|__|__|__|	

ECG				
Inspection date: |_|_|_|_|/|_|_|/|_|_|				□0 Did not check
Heart rate (bpm)	PR interval (ms)	QRS width (ms)	QT interval (ms)	QTC interval (ms)
| __|__|__ |	| __|__|__ |	| __|__|__ |	| __|__|__ |	| __|__|__ |
Check the result	□1Normal □2Abnormalities not clinically significant □3Abnormal clinical significance, please describe:			

Drug release and recall records	
Actual quantity uesd	| __|__ | piece
Recycling actual quantity	| __|__ | piece
Using the actual quantity	| __|__ | piece
Recycling use + indicates to use	

Protocol No.	Screening number	Name abbreviation	Unplanned inspection
KLMS-2019001	|__|__|-|__|__|__|	|__|__|__|__|	

Unplanned inspection

Unplanned inspection □0NO □1Yes, please fill in the form below				
Check the date	**Check items**	**unit**	**Check results**	**Result determination (Please refer to code below)** **1= normal** **2= abnormal no clinical significance** **3= Abnormal clinically significant**
				□1 □2 □3
				□1 □2 □3
				□1 □2 □3
				□1 □2 □3
				□1 □2 □3
				□1 □2 □3
				□1 □2 □3
				□1 □2 □3
				□1 □2 □3
				□1 □2 □3
				□1 □2 □3
				□1 □2 □3
				□1 □2 □3
				□1 □2 □3

Protocol No.	Screening number	Name abbreviation	Unplanned inspection
KLMS-2019001	|__|__|-|__|__|__|	|__|__|__|__|	

project	unit	results	Clinical significance determination 1 2 3 0	Note
Routine blood sampling date: |_|_|_|_|/|_|_|/|_|_| □ did not check				
Red blood cell count (RBC)	X 10^{12}/L		□1 □2 □3 □0	
Hemoglobin (HGB)	g/L		□1 □2 □3 □0	
White Blood cell count (WBC)	X 10^{9}/L		□1 □2 □3 □0	
Platelet count (PLT)	X 10^{9}/L		□1 □2 □3 □0	
Red Blood cell volume (HCT)	%		□1 □2 □3 □0	
Routine urine sampling date: |_|_|_|_|/|_|_|/|_|_| □ did not check				
Protein (PRO)	qualitative		□1 □2 □3 □0	
Urine white blood cells	A/uL		□1 □2 □3 □0	
Urine red blood cells	A/uL		□1 □2 □3 □0	
Blood biochemical sampling date: |_|_|_|_|/|_|_|/|_|_| □ did not check				
Alanine aminotransferase (ALT)	U/L		□1 □2 □3 □0	
Aspartic acid aminotransferase (AST)	U/L		□1 □2 □3 □0	
Total bilirubin (TBIL)	μmol/L		□1 □2 □3 □0	
Glucose (GLU)	mmol/L		□1 □2 □3 □0	
Blood creatinine (Cr)	μmol/L		□1 □2 □3 □0	
Urea nitrogen (BUN)/urea	mmol/L		□1 □2 □3 □0	
Immunology related inspection Sampling date: |_|_|_|_|/|_|_|/|_|_| □ did not check				
Creactive protein (CRP)	μ g/mL		□1 □2 □3 □0	
Procalcitonin (PCT)	ng/mL		□1 □2 □3 □0	
Human Leukocyte Surface Antigen -DR (HLA-DR)	qualitative		□1 □2 □3 □0	
IL6	pg/mL		□1 □2 □3 □0	
IL8	pg/mL		□1 □2 □3 □0	
IL10	pg/mL		□1 □2 □3 □0	
TNF-alpha	ng/mL		□1 □2 □3 □0	
PD-1	qualitative		□1 □2 □3 □0	
Expression of PD-1 in T	qualitative		□1 □2 □3 □0	

cells				
MDSC (myeloid inhibitory cells)	qualitative		□1 □2 □3 □0	
CD4+	A/ul		□1 □2 □3 □0	
CD8+	A/ul		□1 □2 □3 □0	

Protocol No.	Screening number	Name abbreviation	ICU and ventilation
KLMS-2019001	|__|__|-|__|__|__|	|__|__|__|__|	

ICU admission record

Did you stay in the ICU during the trial? □0NO □1Yes, please fill in the following form			
Date of Arrival	**Time of check in**	**Date of departure**	**Time of departure**

Mechanical ventilation record

Was there mechanical ventilation during the test? □0NO □1Yes, please fill in the following form			
Start Date	**Start time**	**End date**	**End time**

CRRT record

Was there CRRT treatment during the trial? □0NO □1Yes, please fill in the following form				
Treatment mode	**Start date**	**Start time**	**End date**	**End time**
□1**dialysis** □2**filtration**				
□1**dialysis** □2**filtration**				

Protocol No.	Screening number	Name abbreviation	Adverse events
KLMS-2019001	|__|__|-|__|__|__|	|__|__|__|__|	

Adverse events

Adverse events

Did any adverse events occur during the trial? □0NO □1Yes, please fill out the following form

Name of Adverse Event	Start date	Start time (HH:MM)	Was it sustained at the end of		End time (HH:MM)	serious The degree of (1)	Dropping out of the trial due to AE?	Measures taken for study drug (2)	Whether treatment was given	Relationship to study drug (3)	Outcome (4)	Is it SAE?
			YES	NO→end date		| __ |	□0NO □1YES	| __ |	□0NO □1YES	| __ |	| __ |	□0NO □1YES
			□			| __ |	□0NO □1YES	| __ |	□0NO □1YES	| __ |	| __ |	□0NO □1YES
			□			| __ |	□0NO □1YES	| __ |	□0NO □1YES	| __ |	| __ |	□0NO □1YES
			□			| __ |	□0NO □1YES	| __ |	□0NO □1YES	| __ |	| __ |	□0NO □1YES

(1) Severity	(2) Measures taken with respect to the investigational drug	And (3) the relationship with the study drug	(4) Outcome

Protocol No.	Screening number	Name abbreviation	Adverse events
KLMS-2019001	|__|__|-|__|__|__|	|__|__|__|__|	

1= Light **2= moderate** **3= severe**	**1= Continue the medication** **2= reduce the dose** **3= Resuming after suspension 4= discontinuing medication** **5= medication has ended** **6= Not applicable**	**1= Definitely relevant** **3= Probably related** **5= Definitely irrelevant**	**2= very likely relevant** **4= Probably unrelated**	**1= disappeared without sequelae** **2= disappeared with sequelae** **3= persistent 4= relief 5= aggravation** **6= Death** **7= unknown**

Protocol No.	Screening number	Name abbreviation	Serious adverse event reports
KLMS-2019001	|__|__|-|__|__|__|	|__|__|__|__|	

Serious adverse event reports

Did any serious adverse events occur during the trial? NO □0 YES □1, if you select "Yes", please fill in the following form:

Type of report	□1First report □2Follow-up report □3Summary Report
SAE name (medical term)	
SAE condition	□1Causing death □2Life-threatening □3Carcinogenic, teratogenic and birth defect □4Cause significant or permanent bodily injury or impairment of organ function resulting in hospitalization or prolonged hospitalization □5Resulting in hospitalization or prolonged hospitalization □6Other important medical events:
SAE occurred date: |__|__|__|__| /|__|__| /|__|__|	**SAE time: |_|_|：|_|_| (24 hours)**
SAE end date: |__|__|__|__| /|__|__| /|__|__|	**The SAE end time: |_|_|：|_|_| (24 hours)**
The SAE reaction severity:	Mild □1 Moderate □2 Severe □3
Measures to be taken for test drug use	□1Continue medication □2Reduce dosage □3Pause and resume □4Discontinue medication □5Medication has ended □6Not applicable
SAE Transfer	□1Symptoms disappear (sequelae have YES□1NO □0) □2Persistent symptoms □3Death (|__|__|__|__| /|__|__| /|__|__|) □4Unknown (for loss of access only)
SAE in relation to the experimental drug	□1Definitely concerned □2Most likely relevant □3May be relevant □4Probably irrelevant □5Definitely irrelevant
Details of the occurrence and handling of SAE:	

Protocol No.	Screening number	Name abbreviation	Standard anti-infective therapy
KLMS-2019001	|__|__|-|__|__|__|	|__|__|__|__|	

Standard anti-infective therapy

Was there a standard anti-infective therapy combined after the informed consent was signed until the end of the study? □0NO □1There are							
Common name	Single dose	unit (1)	way (2)	frequency (3)	Start date	End date	continuous
					|_|_|_|_|/|_|_|/|_|_|	|_|_|_|_|/|_|_|/|_|_|	□1 YES
					|_|_|_|_|/|_|_|/|_|_|	|_|_|_|_|/|_|_|/|_|_|	□1 YES
					|_|_|_|_|/|_|_|/|_|_|	|_|_|_|_|/|_|_|/|_|_|	□1 YES
					|_|_|_|_|/|_|_|/|_|_|	|_|_|_|_|/|_|_|/|_|_|	□1 YES
					|_|_|_|_|/|_|_|/|_|_|	|_|_|_|_|/|_|_|/|_|_|	□1 YES
					|_|_|_|_|/|_|_|/|_|_|	|_|_|_|_|/|_|_|/|_|_|	□1 YES
					|_|_|_|_|/|_|_|/|_|_|	|_|_|_|_|/|_|_|/|_|_|	□1 YES
					|_|_|_|_|/|_|_|/|_|_|	|_|_|_|_|/|_|_|/|_|_|	□1 YES
					|_|_|_|_|/|_|_|/|_|_|	|_|_|_|_|/|_|_|/|_|_|	□1 YES
					|_|_|_|_|/|_|_|/|_|_|	|_|_|_|_|/|_|_|/|_|_|	□1 YES

(1) 1=mg,2=ug,3=g,4=ml,5= others, please specify

(2) 1= oral, 2= intravenous, 3= subcutaneous, 4= subcutaneous push, 5= intramuscular, 6= inhalation, 7= topical, 8= other, please describe in detail

(3) 1= once daily (QD), 2= twice daily (BID), 3= 3 times daily (TID) 4= 4 times daily (QID), 5= 1 every other day (QOD), 6= when necessary (PRN), 7= other, please specify

<table>
<tr><th>Protocol No.</th><th>Screening number</th><th>Name abbreviation</th><th rowspan="2">Combination medication</th></tr>
<tr><td>KLMS-2019001</td><td>|__|__|-|__|__|__|</td><td>|__|__|__|__|</td></tr>
</table>

Combination medication

<table>
<tr><th colspan="10">Were there any other drug combinations between the time the informed consent was signed and the end of the study? □$_0$NO □$_1$YES</th></tr>
<tr><th>Common name</th><th>Single dose</th><th>unit (1)</th><th>way (2)</th><th>frequency (3)</th><th>Reasons for medication</th><th>Whether used to treat AE</th><th>Start date (YYYY/MM/DD)</th><th>End date (YYYY/MM/DD)</th><th>continuous</th></tr>
<tr><td></td><td></td><td></td><td></td><td></td><td></td><td>□$_1$YES□$_0$NO</td><td>|_|_|_|_|/|_|_|/|_|_|</td><td>|_|_|_|_|/|_|_|/|_|_|</td><td>□$_1$ YES</td></tr>
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<tr><td colspan="10">(1) 1=mg,2=ug,3=g,4=ml,5= others, please specify
(2) 1= oral, 2= intravenous, 3= subcutaneous, 4= subcutaneous push, 5= intramuscular, 6= inhalation, 7= topical, 8= other, please describe in detail
(3) 1= once daily (QD), 2= twice daily (BID), 3= 3 times daily (TID) 4= 4 times daily (QID), 5= 1 every other day (QOD), 6= when necessary (PRN), 7= other, please specify</td></tr>
</table>

Protocol No.	Screening number	Name abbreviation	Non-drug Treatments
KLMS-2019001	|__|__|-|__|__|__|	|__|__|__|__|	

Non-drug Treatments

Sign informed consent to the end of the study there non-drug treatment?□0NO □1There are					
Name of treatment	Reason for treatment	Frequency of treatment	Start date	End date	continuous
			|_|_|_|_|/|_|_|/|_|_|	|_|_|_|_|/|_|_|/|_|_|	□1 YES
			|_|_|_|_|/|_|_|/|_|_|	|_|_|_|_|/|_|_|/|_|_|	□1 YES
			|_|_|_|_|/|_|_|/|_|_|	|_|_|_|_|/|_|_|/|_|_|	□1 YES
			|_|_|_|_|/|_|_|/|_|_|	|_|_|_|_|/|_|_|/|_|_|	□1 YES
			|_|_|_|_|/|_|_|/|_|_|	|_|_|_|_|/|_|_|/|_|_|	□1 YES
			|_|_|_|_|/|_|_|/|_|_|	|_|_|_|_|/|_|_|/|_|_|	□1 YES
			|_|_|_|_|/|_|_|/|_|_|	|_|_|_|_|/|_|_|/|_|_|	□1 YES
			|_|_|_|_|/|_|_|/|_|_|	|_|_|_|_|/|_|_|/|_|_|	□1 YES
			|_|_|_|_|/|_|_|/|_|_|	|_|_|_|_|/|_|_|/|_|_|	□1 YES
			|_|_|_|_|/|_|_|/|_|_|	|_|_|_|_|/|_|_|/|_|_|	□1 YES
			|_|_|_|_|/|_|_|/|_|_|	|_|_|_|_|/|_|_|/|_|_|	□1 YES
			|_|_|_|_|/|_|_|/|_|_|	|_|_|_|_|/|_|_|/|_|_|	□1 YES
(1) Treatment frequency: 1=1 time/day;2=2 times/day;3=3 times/day;4=4 times/day;5= others, please specify:					

Research Summary

Research Summary		
Date of completion/exit test: | __|__|__|__ | | __|__ | | __|__ |		
If the subjects according to the research plan finished the entire clinical trial?	□1 YES	□0NO, select the main reason for early exit
Main reasons for early exit (single option) : □1Subject to withdraw from the test; □2Violation of test scheme; □3Adverse events; □4Loss of follow-up; □5The date of death, death: | __|__|__|__ | | __|__ | | __|__ | | __|__ |:| __|__ | The cause of death: □1Sepsis □2Tumor progression □3Unexplained or unwitnessed death □4Other, please describe: □6For other reasons, please describe:		