

Annotated CRF

CM Pharmaceuticals, Inc.

Subject ID 044 - 1 ☐ ☐

Subject Initials ☐ ☐ ☐

INCLUS

Eligibility

Inclusion Criteria (all answers must be YES to be included in the trial)

	Yes	No	
1 Age 18-45 years, inclusive.....	<input type="checkbox"/> 1	<input type="checkbox"/> 0	inc1
2 Willingness to submit to diagnostic machine testing	<input type="checkbox"/> 1	<input type="checkbox"/> 0	inc2
3 Male or non-pregnant, non-lactating female. Women of reproductive potential must be practicing adequate contraception (e.g., intrauterine device or double barrier device such as a diaphragm or condom plus spermicide). Abstinence is not considered to be an acceptable method of contraception. Additionally, women of reproductive potential must have a negative urine pregnancy at screening and prior to enrollment.....	<input type="checkbox"/> 1	<input type="checkbox"/> 0	inc3
4 In good health as determined by medical history and physical examinations.....	<input type="checkbox"/> 1	<input type="checkbox"/> 0	inc4
5 Capable of understanding and complying with the protocol and has signed the informed consent document.....	<input type="checkbox"/> 1	<input type="checkbox"/> 0	inc5

EXCLUS

Exclusion Criteria (all answers must be NO to be included in the trial)

	Yes	No	
1 Pregnant or lactating females.....	<input type="checkbox"/> 1	<input type="checkbox"/> 0	exc1
2 History of anaphylaxis.....	<input type="checkbox"/> 1	<input type="checkbox"/> 0	exc2
3 History or presence of hepatitis.....	<input type="checkbox"/> 1	<input type="checkbox"/> 0	exc3

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subjinit \$3

Demographics/Medical History

DEMO

Demographics	
Sex: sex \$1	Race: race \$9
<input type="checkbox"/> 1 Male	<input type="checkbox"/> 1 Caucasian <input type="checkbox"/> 2 Black <input type="checkbox"/> 3 Hispanic <input type="checkbox"/> 4 Asian
<input type="checkbox"/> 2 Female	<input type="checkbox"/> 5 Other (specify): raceoth \$25
Date of Birth: birthdt	Date Informed Consent Signed : icdt
mm / dd / yy	mm / dd / yy

LABSDONE

Pregnancy test lbdsamp \$42	
Result:	<input type="checkbox"/> 0 Negative lbrescd <input type="checkbox"/> 2 Not applicable

MEDHIST

Medical History		
Body System	Normal	Abnormal (describe)
Neuro mhbodsys \$26	mhstatcd <input type="checkbox"/> 0	mhterm \$200
HEENT	<input type="checkbox"/> 0	
Heart	<input type="checkbox"/> 0	
Lungs	<input type="checkbox"/> 0	
Abdomen	<input type="checkbox"/> 0	
Musculoskeletal	<input type="checkbox"/> 0	
Peripheral Vascular	<input type="checkbox"/> 0	
Skin	<input type="checkbox"/> 0	
Additional Findings: mhafsp \$200		

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Physical Examination

PE

	Study Day 1 <small>peptm \$11</small>		Study Day 2	
Body System	Normal	Abnormal (describe)	Normal	Abnormal (describe)
Neurological <small>pebodsys \$21</small>	<small>pestatcd</small> <input type="checkbox"/> 0	<small>pefind \$160</small>	<input type="checkbox"/> 0	<small>pechgcd</small> <input type="checkbox"/> 1 Unchanged from Study Day 1
HEENT	<input type="checkbox"/> 0		<input type="checkbox"/> 0	<input type="checkbox"/> 1 Unchanged from Study Day 1
Heart	<input type="checkbox"/> 0		<input type="checkbox"/> 0	<input type="checkbox"/> 1 Unchanged from Study Day 1
Lungs	<input type="checkbox"/> 0		<input type="checkbox"/> 0	<input type="checkbox"/> 1 Unchanged from Study Day 1
Abdomen	<input type="checkbox"/> 0		<input type="checkbox"/> 0	<input type="checkbox"/> 1 Unchanged from Study Day 1
Musculoskeletal	<input type="checkbox"/> 0		<input type="checkbox"/> 0	<input type="checkbox"/> 1 Unchanged from Study Day 1
Peripheral Vascular	<input type="checkbox"/> 0		<input type="checkbox"/> 0	<input type="checkbox"/> 1 Unchanged from Study Day 1
Skin	<input type="checkbox"/> 0		<input type="checkbox"/> 0	<input type="checkbox"/> 1 Unchanged from Study Day 1
Additional Findings:			<input type="checkbox"/> 1 Unchanged from Study Day 1	

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Laboratory

LABS	lbptm \$11 Study Day 1	Study Day 2
Name of Lab	lbnamecd lbname \$50	
lbtest \$16 Lab test	Result	Result
	lbstresn	
	<input type="checkbox"/> Not Done	<input type="checkbox"/> Not Done
Sodium		
Potassium		
Chloride		
BUN		
Creatinine		
Total Protein		
Albumin		
Direct bilirubin		
Total bilirubin		
ALT/SGPT		
AST/SGOT		
LDH		
WBC		
Neutrophils		
Eosinophils		
Basophils		
Lymphocytes		
Monocytes		
Hct%		
Hgb		
Platelets		
INR		
PT		
PTT		

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mm dd yy

Evaluations and Dosing

VITAL

visit
\$11

Baseline Vital Signs					
Time (24 Hour)	Temp (°F)	HR (per minute)	RR (per minute)	BP (syst/dia)	O ₂ Sat (%)
vsacttm :	temp	heart	resp	sysbp /diabp	o2sat

VITAL

HQSCORE

Weight	Height	Health Questionnaire Score	
<u>weight</u> <u>weightun</u> Kg	<u>height</u> <u>heightun</u> inches	Pre <u>mmtm</u> mmscore	\$24 Post

EXPOSURE

period

Cohort	Infusion Period # 1	Infusion Period # 2
1 <input type="checkbox"/> <u>cohort</u>	<u>modecd</u> <u>mode</u> <input type="checkbox"/> ₁ Bottle 12.5 mg/kg	<input type="checkbox"/> ₁ Bottle 12.5 mg/kg
2 <input type="checkbox"/>	<input type="checkbox"/> ₂ Bag 6.25 mg/kg	<input type="checkbox"/> ₂ Bag 6.25 mg/kg
	<input type="checkbox"/> ₃ Bag, other <u>0</u> . <u> </u> <u> </u> <u> </u>	<input type="checkbox"/> ₃ Bag, other <u>0</u> . <u> </u> <u> </u> <u> </u>
	Amount PROD infused	Amount PROD infused
<input type="checkbox"/> Other <u> </u>	<u>proddose</u> _____ . _____ mg	_____ . _____ mg

Study Day 1

Vital Signs

VITALTPT \$31

Timepoint	Time (24 Hour)	HR (per min)	BP (syst/dia)	O ₂ Sat (%)
- 5 minutes	vsacttm :	heart	sysbp / diapb	o2sat
0 minutes	:		/	
5 minutes	:		/	
10 minutes	:		/	
15 minutes	:		/	
20 minutes	:		/	
25 minutes	:		/	
30 minutes	:		/	
35 minutes	:		/	
40 minutes	:		/	
45 minutes	:		/	
50 minutes	:		/	
55 minutes	:		/	
60 minutes	:		/	
65 minutes	:		/	
70 minutes	:		/	
End of Infusion Period #2	:			
1 hour after Infusion Period #2	:		/	

CONMEDS

Concomitant Medications

☐ None cmanycd

Medication		Dose	Unit	Route	Date (mm / dd / yy)	Time (24 Hour)
1	cmterm \$80	cmdose \$10	cmunit \$10	cmroute \$10	cmstdtc \$10 ____/____/____	cmtm : :
2	Coding: cmprefcd \$11 - WHO Drug Code				____/____/____	:
3	cmatccd \$5 - ATC Code cmatc \$50 - ATC Text				____/____/____	:
4					____/____/____	:
5					____/____/____	:
6					____/____/____	:
7					____/____/____	:
8					____/____/____	:
9					____/____/____	:
10					____/____/____	:
11					____/____/____	:
12					____/____/____	:

☐ Check if subsequent pages

Report all Serious Adverse Events
IMMEDIATELY

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AE

Adverse Events

☐ None [aeanycd](#)

Event Description		Onset	Resolution	Severity	Relationship to PROD	Actions taken (✓ all applicable)
1	aeterm \$120	Date (mm/dd/yy) aestdt <input type="text"/>	aeendt <input type="text"/>	<input type="checkbox"/> 1 Mild <input type="checkbox"/> 2 Moderate <input type="checkbox"/> 3 Severe <input type="checkbox"/> 4 Life-threatening aesevcd	<input type="checkbox"/> 1 Unrelated <input type="checkbox"/> 2 Possibly <input type="checkbox"/> 3 Probably <input type="checkbox"/> 4 Definitely aerelcd	<input type="checkbox"/> 0 None aenoatcd <input type="checkbox"/> 1 Treatment aetxcd <input type="checkbox"/> 2 PROD stopped aeprncd <input type="checkbox"/> 3 Discontinued trial aedccd <input type="checkbox"/> 4 SAE Reported aesercd
		Time (24 hour) :	aesttm : <input type="checkbox"/> 1 Continuing aeongocd			
2		Date (mm/dd/yy) <input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Mild <input type="checkbox"/> 2 Moderate <input type="checkbox"/> 3 Severe <input type="checkbox"/> 4 Life-threatening	<input type="checkbox"/> 1 Unrelated <input type="checkbox"/> 2 Possibly <input type="checkbox"/> 3 Probably <input type="checkbox"/> 4 Definitely	<input type="checkbox"/> 0 None <input type="checkbox"/> 1 Treatment <input type="checkbox"/> 2 PROD stopped <input type="checkbox"/> 3 Discontinued trial <input type="checkbox"/> 4 SAE Reported
		Time (24 hour) :	<input type="checkbox"/> 1 Continuing			
3		Date (mm/dd/yy) <input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Mild <input type="checkbox"/> 2 Moderate <input type="checkbox"/> 3 Severe <input type="checkbox"/> 4 Life-threatening	<input type="checkbox"/> 1 Unrelated <input type="checkbox"/> 2 Possibly <input type="checkbox"/> 3 Probably <input type="checkbox"/> 4 Definitely	<input type="checkbox"/> 0 None <input type="checkbox"/> 1 Treatment <input type="checkbox"/> 2 PROD stopped <input type="checkbox"/> 3 Discontinued trial <input type="checkbox"/> 4 SAE Reported
		Time (24 hour) :	<input type="checkbox"/> 1 Continuing			
4		Date (mm/dd/yy) <input type="text"/>	<input type="text"/>	<input type="checkbox"/> 1 Mild <input type="checkbox"/> 2 Moderate <input type="checkbox"/> 3 Severe <input type="checkbox"/> 4 Life-threatening	<input type="checkbox"/> 1 Unrelated <input type="checkbox"/> 2 Possibly <input type="checkbox"/> 3 Probably <input type="checkbox"/> 4 Definitely	<input type="checkbox"/> 0 None <input type="checkbox"/> 1 Treatment <input type="checkbox"/> 2 PROD stopped <input type="checkbox"/> 3 Discontinued trial <input type="checkbox"/> 4 SAE Reported
		Time (24 hour) :	<input type="checkbox"/> 1 Continuing			

Coding: [aeprefcd \\$8 - MEDRA Term](#)

[aedecod \\$100 - Medra Preferred Term](#)

[aesoccd \\$8 - SOC Code](#)

[aesoc \\$100 - SOC Text](#)

Investigator's Signature

Date

☐ 1 Check if subsequent pages

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Study Day 2 / ^{visdt} / Study Completion

Study Completion/Termination ^{VITAL}

Vital Signs					
Time (24 Hour)	Temp (°F)	HR (per minute)	RR (per minute)	BP (syst/dia)	O ₂ Sat (%)
:				/	

Did the subject complete the trial ? ☐ ₁ Yes ☐ ₀ No ^{dsstatcd}

If No, please complete the following (✓ all applicable) ^{DISPOSIT}

Reason for discontinuation		Date mm / dd / yy	
<input type="checkbox"/> ₁	Adverse Event ^{dsaecd}	<input type="text"/> / <input type="text"/> / <input type="text"/> ^{dsaedt}	event: ^{dsaesp \$140}
<input type="checkbox"/> ₂	Withdrew consent ^{dswdcd}	<input type="text"/> / <input type="text"/> / <input type="text"/> ^{dswddt}	reason: ^{dswdsp \$40}
<input type="checkbox"/> ₃	Lost to follow up ^{delostcd}	<input type="text"/> / <input type="text"/> / <input type="text"/> ^{dslostdt}	reason: ^{dslostsp \$140}
<input type="checkbox"/> ₄	Blood clot ^{dsclostcd}	<input type="text"/> / <input type="text"/> / <input type="text"/> ^{dsshntdt}	
<input type="checkbox"/> ₅	Other ^{dsothcd}	<input type="text"/> / <input type="text"/> / <input type="text"/> ^{dsothdt}	specify: ^{dsothsp \$200}

Summary of Protocol Compliance

Was the protocol followed without deviations? ☐ ₁ Yes ☐ ₀ No ^{departcd}

If No, please complete the following (✓ all applicable) ^{SUMMARY}

Departures		
<input type="checkbox"/> ₁	Entrance Criteria ^{reascd} not met	specify: ^{reassp1 \$200}
<input type="checkbox"/> ₂	PROD not administered fully	reason: ^{reassp2 \$200}
<input type="checkbox"/> ₃	Images not obtained	explain:
<input type="checkbox"/> ₄	Safety data not obtained or not collected at scheduled time point	explain:
<input type="checkbox"/> ₅	Other	specify: