

APPENDIX 1

CASE REPORT FORM

**DIHYDROARTEMISININ MONOTHERAPY COMPARED WITH
DIHYDROARTEMISININ-MEFLOQUINE COMBINATION THERAPY
IN TREATMENT OF
UNCOMPLICATED FALCIPARUM MALARIA**

Cho Ray Hospital, Ho Chi Minh City, Vietnam

Bac Binh District Hospital, Binh Thuan Province

Song Luy Health Post, Bac Binh District, Binh Thuan Province

Mepu Health Post, Duc Linh District, Binh Thuan Province

11st Plantation Health Post, Phu Rieng Rubber Company, Binh Phuoc Province

2000

Study site: _____
 Ward: _____

Study code: **DHA/DHA+MQ**
 Patient code: _____
 Patient initials: _____

CASE REPORT FORM SUMMARY

1/ PATIENT DETAILS

Patient initials: _____		Age (yrs): _____
Gender: Male: <input type="checkbox"/>	Female: <input type="checkbox"/>	Weight (kg): _____
Admission date (d/m/y): _____ / _____ / _____		Height (cm): _____
Discharge date (d/m/y): _____ / _____ / _____		Province: _____
Last date of follow-up (d/m/y): _____ / _____ / _____		Occupation: _____

2/ DIAGNOSIS

UCFM <input type="checkbox"/>	Initial parasitemia count (/μl): _____	Axillary temperature (°C): _____
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3/ TREATMENT

DHA+MQ <input type="checkbox"/>	DHA <input type="checkbox"/>
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4/ INITIAL CLINICAL RESPONSE

Result	Good <input type="checkbox"/> (fever subsidence + parasite clearance)	Failure <input type="checkbox"/> (Changes into the SCFM, or RIII, or RII)
If the patient condition changes into the SCFM		At time (h) _____ (counting from t=0 on admission)
If GOOD	Fever clearance time (h)	Not available <input type="checkbox"/>
	Parasite clearance time (h) PCT 100% _____ PCT 95% _____ PCT 50% _____	Not available <input type="checkbox"/>

5/ PARASITOLOGICAL RESPONSE

RIII response <input type="checkbox"/>	At time (h): _____ (counting from t=0)	
RII response <input type="checkbox"/>	At time (h): _____ (counting from t=0)	
28-day Follow-up	No: <input type="checkbox"/>	Complete: <input type="checkbox"/> Incomplete: <input type="checkbox"/>
RI response (counting from d0) <input type="checkbox"/>	Early RI <input type="checkbox"/> At day (d) _____	Late RI <input type="checkbox"/> At day (d) _____
Radical cure <input type="checkbox"/>		

6/ SIDE EFFECTS

Number of side effects: _____

Name of side effect	At time (counting from t=0)	Severity (1: mild; 2: moderate, 3: severe)	Special intervention
_____	_____	_____	_____
_____	_____	_____	_____

Investigator:

Signature:

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Patient initials: _____ Date of birth (d/m/y): ___/___/___ Age (yrs): _____
Gender: Male Female Occupation: _____
Province: _____ District: _____ Village: _____
Date of admission (d/m/y): ___/___/___

PAST HISTORY

Has the patient been living in the malarial area? Yes No
If yes, how many years? _____
Did the patient have positive malaria in the past two years? Yes No
If yes, how many times? _____
Did the patient have severe and complicated falciparum malaria in the past two years?
Yes No
If yes, how many times? _____
The last time treated with mefloquine in the past two months?
Date (d/m/y): ___/___/___

PRESENT ILLNESS

When did the patient have the first malarial episode? Date (d/m/y): ___/___/___ At time _____
How many malarial episodes did the patient have before admission? _____
Did the patient receive any treatment before admission? Yes No
If yes, when did the patient receive the treatment? Date (d/m/y): ___/___/___
What was the treatment? (Describe: name of drug, dose/day, duration?...)

Name of drug	Dose/day	How many days?	Others
_____	_____	_____	_____
_____	_____	_____	_____

INCLUSION, EXCLUSION CRITERIA

Inclusion criteria	Exclusion criteria
- Male or female aged from 15 - 60	<input type="checkbox"/> - Age less than 15 or older than 60
- <i>P. falciparum</i> (+) with initial parasitemia count (1,000 - 200,000/ μ l)	<input type="checkbox"/> - Pregnancy: dipstick test (+)
- Uncomplicated falciparum malaria	- Lactation <input type="checkbox"/>
	- Severe & complicated falciparum malaria <input type="checkbox"/>
	- Administration of
	. artemisinin or its derivatives \leq 12 h <input type="checkbox"/>
	. quinine \leq 12 h <input type="checkbox"/>
	. tetracycline \leq 7 days <input type="checkbox"/>
	. mefloquine \leq 21 days <input type="checkbox"/>
	- Inability to take oral medication <input type="checkbox"/>
	- Known allergy to study drugs <input type="checkbox"/>

Tick off (\checkmark) in the corresponding cells () if the criteria are fit to the patient.

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TREATMENT

Which regimen was randomly assigned?

DHA+MQ <input type="checkbox"/>	DHA <input type="checkbox"/>
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Regimen	DHA+MQ			
Date (d/m/y)	Time (am, pm)	Schedule time (h)	Drug	Dose (mg)
___/___/___	_____	0 h	DHA	300
___/___/___	_____	24 h	DHA	300
___/___/___	_____	24 h	MQ	750

Regimen	DHA			
Date (d/m/y)	Time (am, pm)	Schedule time (h)	Drug	Dose (mg)
___/___/___	_____	0 h	DHA	300
___/___/___	_____	24 h	DHA	300
___/___/___	_____	48 h	DHA	100
___/___/___	_____	72 h	DHA	100
___/___/___	_____	96 h	DHA	100

Dihydroartemisinin: 100 mg/capsule (Drafa-Pharma Pharmaceutical Company, Brussels).
 Mefloquine: 250 mg/tablet (Euphaquine®, Switzerland).

CLINICAL INVESTIGATION

	d0	___/___/___ d1		___/___/___ d2		___/___/___ d3		___/___/___ d4		___/___/___ d5		___/___/___ d6		___/___/___ d7	
	0h	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm
Fever															
Chill															
Sweating															
Hepatomegaly															
Splenomegaly															

		___/___/___ d14		___/___/___ d21		___/___/___ d28		___/___/___ d35		___/___/___ d42	
		am	pm	am	pm	am	pm	am	pm	am	pm
Fever											
Chill											
Sweating											
Hepatomegaly											
Splenomegaly											

Fever, Chill, Sweating: 3 (severe), 2 (moderate), 1 (mild), 0 (normal); Hepatomegaly: the extent (cm) below right costal margin; Splenomegaly: Hackett's method (from 1 to 5).

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VITAL SIGNS

Date (d/m/y)	Time for 24 h (am, pm)	Schedule time (h)	Blood pressure (mmHg)	Heart rate (beats/min)	Respiratory rate (times/min)	Axillary temperature (°C)
/ /		0				
/ /		6				
/ /		12				
/ /		18				
/ /		24				
/ /		30				
/ /		36				
/ /		42				
/ /		48				
/ /		54				
/ /		60				
/ /		66				
/ /		72				
/ /		78				
/ /		84				
/ /		90				
/ /		96				
/ /		d5				
/ /		d6				
/ /		d7				
/ /		d8				
/ /		d10				
/ /		d12				
/ /		d14				
/ /		d16				
/ /		d18				
/ /		d20				
/ /		d21				
/ /		d22				
/ /		d24				
/ /		d26				
/ /		d28				
/ /		d35				
/ /		d42				
/ /		d49				

Fever Clearance Time FCT (h): _____

Study site: _____
 Ward: _____

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PARASITOLOGICAL INVESTIGATION

Date (d/m/y)	Time for 24 h (am,pm)	Schedule time (h)	Parasite count (/µl)	Date (d/m/y)	Time for 24 h (am,pm)	Schedule time (h)	Parasite count (/µl)
/ /		0		/ /		d5	
/ /		6		/ /		d6	
/ /		12		/ /		d7	
/ /		18		/ /		d10	
/ /		24		/ /		d12	
/ /		30		/ /		d14	
/ /		36		/ /		d16	
/ /		42		/ /		d18	
/ /		48		/ /		d20	
/ /		54		/ /		d22	
/ /		60		/ /		d24	
/ /		66		/ /		d26	
/ /		72		/ /		d28	
/ /		78		/ /		d35	
/ /		84		/ /		d42	
/ /		90		/ /			
/ /		96		/ /			

Blood smears will be done at t=0 (on admission) and every 6 hours until 3 consecutive negative blood smears, then daily during the first week, then once weekly until day 28.

Parasite Clearance Time PCT (h)

PCT100% _____ PCT95% _____ PCT50% _____

RIII response	<input type="checkbox"/>	At time	Additional treatment	
RII response	<input type="checkbox"/>	At time	Additional treatment	
Follow-up				
28 days	<input type="checkbox"/>	42 days	<input type="checkbox"/>	Complete
			<input type="checkbox"/>	Incomplete
				Reasons
RI response	<input type="checkbox"/>	Early RI	<input type="checkbox"/>	At day _____ Parasite count _____ (/µl)
		Late RI	<input type="checkbox"/>	At day _____ Parasite count _____ (/µl)
Radical cure	<input type="checkbox"/>			

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LABORATORY INVESTIGATION

	Normal values	d0 t=0	_/ _ / _ d2	_/ _ / _ d4	_/ _ / _ d7	_/ _ / _ d14	_/ _ / _ d28
HEMATOLOGY							
Hct (%)	40 - 54	_____	_____	_____	_____	_____	_____
Hb (g/dl)	14 - 18	_____	_____	_____	_____	_____	_____
RBC (x10 ⁶ /μl)	4.5 - 6.0	_____	_____	_____	_____	_____	_____
WBC (x10 ³ /μl)	5.0 - 10.0	_____	_____	_____	_____	_____	_____
Neutrophil (%)	54 - 62	_____	_____	_____	_____	_____	_____
Lymphocyte (%)	25 - 33	_____	_____	_____	_____	_____	_____
Monocyte (%)	2 - 7	_____	_____	_____	_____	_____	_____
Eosinophil (%)	1 - 3	_____	_____	_____	_____	_____	_____
Basophil (%)	0 - 1	_____	_____	_____	_____	_____	_____
Platelet (x10 ⁵ /μl)	2.0 - 5.0	_____	_____	_____	_____	_____	_____
Reticulocyte (%)	0.5 - 1.5	_____	_____	_____	_____	_____	_____
BIOCHEMISTRY							
Total protein (g/dl)	6.3 - 8.3	_____	_____	_____	_____	_____	_____
Albumin (g/dl)	3.5 - 5.0	_____	_____	_____	_____	_____	_____
Alk.P. (U/l)	98 - 279	_____	_____	_____	_____	_____	_____
AST (U/l)	9 - 35	_____	_____	_____	_____	_____	_____
ALT (U/l)	7 - 45	_____	_____	_____	_____	_____	_____
Total bili. (mg/dl)	0.2 - 1.2	_____	_____	_____	_____	_____	_____
BUN (mg/dl)	7 - 20	_____	_____	_____	_____	_____	_____
Creatinine (mg/dl)	0.6 - 1.4	_____	_____	_____	_____	_____	_____
Glucose (mg/dl)	65 - 110	_____	_____	_____	_____	_____	_____
URINALYSIS							
Color, turbidity		_____	_____	_____	_____	_____	_____
Specific gravity	1.002 -	_____	_____	_____	_____	_____	_____
pH	1.030	_____	_____	_____	_____	_____	_____
Albumin	5 - 7	_____	_____	_____	_____	_____	_____
Sugar	0	_____	_____	_____	_____	_____	_____
Bilirubin	0	_____	_____	_____	_____	_____	_____
RBC (cells/h.p.f.)	0	_____	_____	_____	_____	_____	_____
WBC (cells/h.p.f.)	2 - 3	_____	_____	_____	_____	_____	_____
Epith. (cells/h.p.f.)	4 - 5	_____	_____	_____	_____	_____	_____
Casts	2 - 6	_____	_____	_____	_____	_____	_____
Others	0	_____	_____	_____	_____	_____	_____

The hematological and biological tests are done accordingly to the routine practice of the hospital.

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SIDE EFFECTS

	Time after drug administration (d0)																	
	t=0	d1		d2		d3		d4		d5		d6		d7		d14	d21	d28
		a	p	a	p	a	p	a	p	a	p	a	p	a	p			
Vomiting																		
Nausea																		
Abdominal pain																		
Diarrhea																		
Anorexia																		
Dry mouth																		
Excess salivation																		
Weakness																		
Dizziness																		
Tinnitus																		
Headache																		
Confusion																		
Joint pain																		
Tremor																		
Itching																		
Skin rash																		
Hair bleaching																		
Blurred vision																		
Palpitation																		

Fill in the cells as: 0 (normal); 1 (mild); 2 (moderate); 3 (severe); or ND (not done).