

CHAPTER 6: APPENDIX

6.1: Patients information sheet

Abbreviations: TWC = total white blood cell, HB: Hemoglobin

<i>Patient ID</i>	<i>Age</i>	<i>Gender</i>	<i>TWC</i>	<i>HB</i>	<i>Platelets</i>	<i>Blast (%)</i>
<i>No.</i>			<i>(x10⁹/L)</i>	<i>(g/dl)</i>	<i>(x10⁹/L)</i>	
606	0	Male	152.8	7.1	10	94
927	1	Male	206.2	2.2	166	80
934	1	Female	44.8	8	6	10
1042	1	Male	90	8.8	29	84
1045	1	Male	40.9	5.9	26	9
1102	1	Female	25.9	5.2	47	84
1150	1	Male	17.9	14.3	49	40
1151	1	Male	12.2	5.9	41	3
1167	1	Female	7.6	5.8	27	20
1190	1	Male	68.8	10.6	63	
444	2	Female	168.5	4.8	61	91
905	2	Male	117.3	5.8	23	97
1101	2	Male	16.2	7.8	63	19
1166	2	Female	3	8.2	175	80
1220	2	Male	28.8	8.2	43	5
1232	2	Female	13.2	9.4	16	74
1238	2	Male	102	4.4	4	-
423	3	Male	13.9	5.8	42	-
738	3	Male	8.5	6.6	20	4
1039	3	Male	309.3	35	26	94

1057	3	Female	145.8	9.1	71	58
1076	3	Female	194.9	5.6	33	90
1286	3	Female	106	116	88	55
1292	3	Male	708	6.4	16	94
319	4	Female	5.5	11.6	240	1
359	4	Female	22.6	8.9	10	50
587	4	Female	6.4	10.7	57	17
1084	4	Male	2.8	8.8	1.58	-
1204	4	Male	5.3	10.5	29	21
1222	4	Male	11.9	10.2	202	17
1228	4	Male	19.3	3.8	4	26
1237	4	Male	279	9.6	32	82
1257	4	Male	7.2	2.8	70	57
1259	4	Male	26.7	12.7	200	200
338	5	Male	0.6	8.2	29	-
454	5	Female	2.9	4.7	13	6
858	5	Female	2	99	9	9
1077	5	Male	19.4	9.2	75	68
1121	5	Male	22	5.3	16	63
1186	5	Female	34.4	7.3	56	89
1205	5	Male	2	-	-	-
1252	5	Female	4.8	6.3	37	11
835	6	Male	8.5	97	70	14
941	6	Male	60.6	92	83	75
948	6	Male	5.2	83	18	28
1233	6	Male	160.5	5.7	21	93

472	7	Female	6.7	11.5	365	0
486	7	Male	31.5	10.7	53	80
500	7	Male	12.2	8	7	64
665	7	Male	4.8	4.3	25	-
893	7	Male	4.3	58	146	19
570	8	Male	1.5	3.7	11	17
577	9	Male	28.1	6.1	57	45
1058	9	Female	151.9	5.7	23	93
1070	9	Female	143	5.1	44	90
1195	9	Female	4.8	8.5	176	-
456	10	Female	25.3	4.93	116	-
871	10	Male	25	5.1	74	80
884	10	Male	421.7	80	77	93
919	10	Male	8.8	9	573	1
1072	10	Female	68	10.9	52	87
1124	10	Male	6.2	8.3	63	34
1283	10	Female	4.7	8.3	166	-
872	11	Male	106	116	88	55
453	12	Male	623.7	4	32	95
540	12	Male	38.7	9.4	221	70
837	12	Male	3.1	8.3	184	1
1141	12	Male	246	10.7	38	90
932	13	Female	33.1	5.1	30	78
771	14	Female	6.5	9.6	17	3
1231	14	Male	19.9	12.1	14	-
1041	15	Female	3.6	12.3	242	38

6.2: Patient information sheet for chemotherapy and cell banking

BIK-MIS-883-E01



KEBENARAN UNTUK MENERIMA RAWATAN KEMOTERAPI MENURUT PROTOKOL MA-SPORE 2002 DAN PENYIMPANAN BAKI SEL LEUKEMIA UNTUK PERBANKAN SEL (CELL BANKING)

Saya No Kad Pengenalan

beralamat

dengan ini mengizinkan anak/jagaan saya untuk menerima rawatan bagi penyakit acute lymphoblastic leukaemia (ALL) menurut protokol MA-SPORE 2002 serta pengambilan sample sum-sum tulangnya untuk kajian sisa sel leukemia. Kesan dan risikonya telah diterangkan kepada saya oleh

Dr (*Nama Doktor yang Merawat*) yang telah menerangkan kepada saya dengan sepenuh kemampuan dan kebolehannya sifat, tujuan, kesan dan risiko di atas dengan terang dan jelas.

Saya juga memberi keizinan supaya baki sel-sel leukemia yang diperolehi daripada darah atau sum-sum tulang anak/jagaan saya di atas disimpan di makmal onkologi pediatrik, National University of Singapore, iaitu makmal pusat bagi kajian ini, untuk tujuan kajian saintifik di masa-masa hadapan jika perlu. Saya telah diberi jaminan bahawa segala maklumat peribadi anak/jagaan saya akan terpelihara sepanjang waktu.

Tarikh :
Pertalian dengan pesakit T/tangan waris yang bertanggungjawab

DI HADAPAN

Nama Tandatangan

No. Kad Pengenalan (*Saksi untuk Tandatangan*)

Jawatan

Saya sahkan bahawa saya telah menerangkan kepada waris yang bertanggungjawab sifat, tujuan, kesan dan risiko prosedur tersebut diatas. Pada pendapat saya waris yang bertanggungjawab telah memahami penerangan ini..

Tarikh..... Tandatangan
(Doktor yang Merawat)

6.3: Consent form for bone marrow cell collection.

Code: KL_



CONSENT FOR COLLECTION OF BONE MARROW SAMPLE FOR CELL BANKING

I, Identity Card Number.....

of
(Address)

hereby consent to the submission of..... for
(Name of patient)

bone marrow aspiration for the purpose of diagnosis and assessment of disease status whilst receiving treatment for leukemia at the University of Malaya Medical Centre, Kuala Lumpur.

I also consent to the **storage of excess bone marrow cells** in a cell bank at the Paediatric Oncology Laboratory of the National University of Singapore for the purpose of future research if required.

I have been assured that in no way will my child's confidentiality be breached for any purpose.

Relationship to patient Signature

IN THE PRESENCE OF

Name Signature

Identity Card No..... (Witness for Signature of responsible relative)

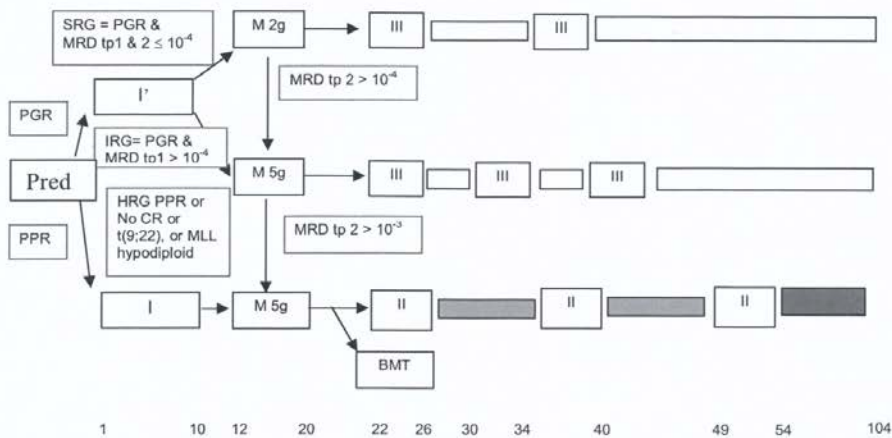
Designation

I confirm that I have explained to the above-signed relative the nature, purpose, effect and risks of the above-mentioned procedure. In my opinion he/she understood this explanation.

Date : Signature
(Attending Doctor)

6.4 Protocol MA-SPORE-ALL-2003 treatment overview

Ma-Spore ALL 2003 protocol



Ma-Spore ALL-2003 Study

Treatment overview

1. Induction (Protocol I) – 10 weeks

Prednisolone 60 mg/m²/day p.o. from day 1 -7
IT MTX

1a' (for SR and IR group)

Dexamethasone 6mg/m²/day from day 8 to 35
IV Vincristine 1.5mg/m²/dose weekly for week 2,3,4,5
IM L-asparaginase 7,500 U/m²/dose from day 8 twice a week for 8 doses (4 weeks)
If allergic to E coli L-asp, switch to PEG L-asp 2,500U/m²/dose weekly. X 4 weeks. If this is too costly, drug is omitted.
IT MTX at day 8, d15, d33

1a (for HR group – prednisolone poor responders only)

Dexamethasone 6mg/m²/day from day 8 to 35
IV Vincristine 1.5mg/m²/dose weekly for week 2,3,4,5

IV Daunorubicin 25 mg/m²/dose weekly for week 2,3,4,5
IM L-asparaginase 7,500 U/m² from day 8 twice a week for 8 doses (4 weeks)
If allergic to E coli L-asp, switch to PEG L-asp 2,500U/m²/dose weekly. X 4 weeks. If this is too costly, drug is omitted.
IT MTX at day 8, d15, d33

1b (all groups)

IV cyclophosphamide 1000mg/m² day 36 and 64
Mercaptopurine p.o. 50mg/m²/day ON
IV or S/c cytarabine 75mg/m² for 4 days block X 4 blocks
IT MTX at day 45, 59 (beginning of the 2nd and 4th block of cytarabine)

2. Protocol M'/M (8 weeks)

Protocol M' for SR group

IV HDMTX 2000mg/m² every 2 weeks with folinic rescue X 4 weeks
IV folinic acid 15mg/m²/dose at 42, 48, 54 hours from start of IV MTX
Mercaptopurine p.o. 25mg/m²/day ON
IT MTXwith each HDMTX

Protocol M for IR/HR

IV HDMTX 5000mg/m² every 2 weeks with folinic rescue X 4 weeks
IV folinic acid 15mg/m²/dose at 42, 48, 54 hours from start of IV MTX
Mercaptopurine p.o. 25mg/m²/day ON
IT MTXwith each HDMTX

3. Protocol III (4 weeks) – SR and IR

Dexamethasone p.o. 10mg/m²/day for 14 days,
IV Vincristine 1.5 mg/m²/dose week on days 0, 7
IV doxorubicin 30 mg/m²/dose every week on days 0, 7
IM L-Asparaginase 10,000U/m²/day twice a week from day 3 for 4 doses
If allergic to E coli L-asp, switch to PEG L-asp 2,500U/m²/dose weekly. X 4 weeks. If this is too costly, drug is omitted.

IV cyclophosphamide 500mg/m² on day 15
IV or S/c cytarabine 75 mg/m²/dose for 4 days blocks X 2 blocks
Thioguanine 50mg/m²/day ON for 2 weeks from day 14-28
IT MTX on start of every cytarabine block (total of 2 IT)

4. Protocol II' (5 weeks) - HR

Dexamethasone 10mg/m²/day p.o. for 21 days

IV Vincristine 1.5mg/m² on days 0, 7, 14
IV doxorubicin 25mg/m² on days 0, 7, 14
IM L-asparaginase 10,000U/m²/dose twice weekly from day 3 for 2 wks
If allergic to E coli L-asp, switch to PEG L-asp 2,500U/m²/dose weekly. X 4 weeks. If this is too costly, drug is omitted.

IV Cyclophosphamide 1000mg/m² on day 21
Thioguanine p.o. 50mg/m² ON
IV cytarabine 75mg/m²/dose for 4 days block X 2 blocks
IT MTX on start of every cytarabine block (total of 2 IT)

5. Interim maintenance HR

IV vincristine 1.5 mg/m² per week for 8 weeks
IV methotrexate 100mg/m²/dose wkly
IM L-asparaginase 15,000U/m² every week for 8 weeks
If allergic to E coli L-asp, switch to PEG L-asp 2,500U/m²/dose weekly. If this is too costly, drug is omitted and switch to IR interim maintenance.
IT MTX every fortnight X 4 doses

6. HR maintenance (12 weeks cycles till 2 years)

IV vincristine 1.5 mg/m² every 4 wks
Dexamethasone p.o. 10mg/m²/day for 7 days every 4 weeks
Mercaptopurine p.o. **75mg/m²/day** ON
Methotrexate p.o. 20mg/m²/dose weekly ON
IT MTX on week 1 of cycle

7. Interim maintenance SR or IR

Mercaptopurine p.o. 50 mg/m²/day ON
Methotrexate 20mg/m² weekly ON
IT triple every 8 weeks

8. SR and IR maintenance (12 weeks cycles till 2 years)

Mercaptopurine p.o. 50mg/m²/day ON
Methotrexate 20mg/m²/dose weekly ON
IV vincristine 1.5 mg/m²/dose at week 11 and 12
Dexamethasone 6mg/m²/day for 7 days at week 11
IT MTX at week 11 and 12

Cranial radiotherapy only for patients with CNS leukaemia or WBC > 100,000/uL at presentation. After RT, no IT after that.