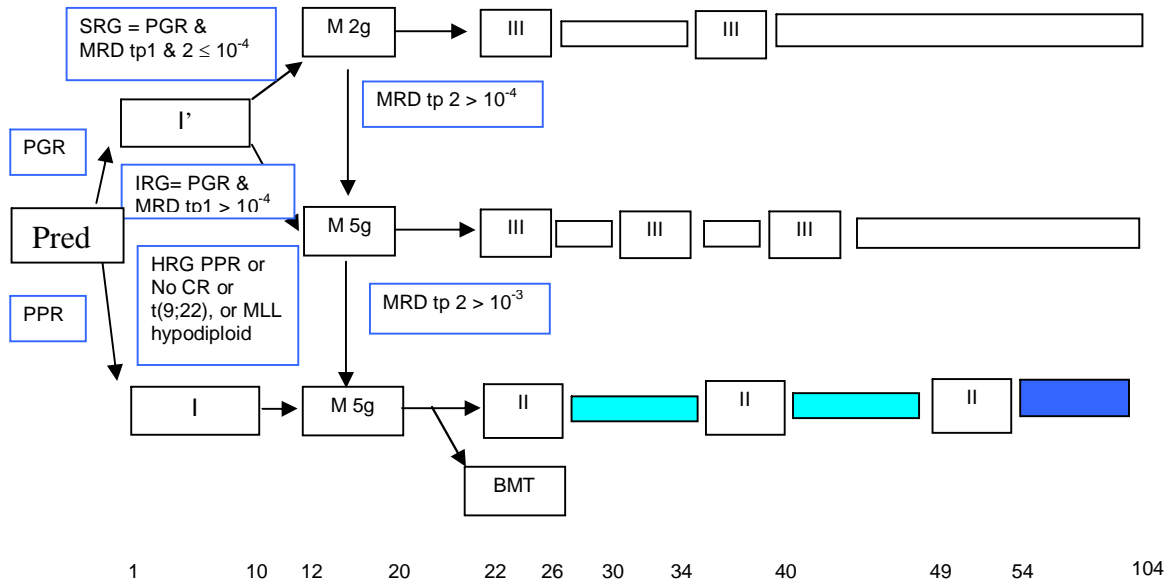


Ma-Spore ALL 2003 protocol



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

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

IV Cyclophosphamide $1000\text{mg}/\text{m}^2$ on day 21
Thioguanine p.o. $50\text{mg}/\text{m}^2$ ON
IV cytarabine $75\text{mg}/\text{m}^2/\text{dose}$ 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 $1.5\text{ mg}/\text{m}^2$ per week for 8 weeks
IV methotrexate $100\text{mg}/\text{m}^2/\text{dose}$ wkly
IM L-asparaginase $15,000\text{U}/\text{m}^2$ every week for 8 weeks
If allergic to E coli L-asp, switch to PEG L-asp $2,500\text{U}/\text{m}^2/\text{dose}$ 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 $1.5\text{ mg}/\text{m}^2$ every 4 wks
Dexamethasone p.o. $10\text{mg}/\text{m}^2/\text{day}$ for 7 days every 4 weeks
Mercaptopurine p.o. **$75\text{mg}/\text{m}^2/\text{day}$** ON
Methotrexate p.o. $20\text{mg}/\text{m}^2/\text{dose}$ weekly ON
IT MTX on week 1 of cycle

7. Interim maintenance SR or IR

Mercaptopurine p.o. $50\text{ mg}/\text{m}^2/\text{day}$ ON
Methotrexate $20\text{mg}/\text{m}^2$ weekly ON
IT triple every 8 weeks

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

Mercaptopurine p.o. $50\text{mg}/\text{m}^2/\text{day}$ ON
Methotrexate $20\text{mg}/\text{m}^2/\text{dose}$ weekly ON
IV vincristine $1.5\text{ mg}/\text{m}^2/\text{dose}$ at week 11 and 12
Dexamethasone $6\text{mg}/\text{m}^2/\text{day}$ for 7 days at week 11
IT MTX at week 11 and 12

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