

NCIC CE.6
EORTC 26062-22061
TROG 08-02

A randomised phase III study of temozolomide and short-course radiation versus radiation alone in the treatment of newly diagnosed glioblastoma multiforme in elderly patients.



Schema

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Newly diagnosed GBM
≥ 65
ECOG 0-2
Biopsy or resection
Not fit for 60Gy in 30

Radiation Alone
40Gy / 15 / 5 3wks

Radiation + Temozolomide
40Gy / 15 / 5 3wks
and adjuvant Temozolomide
up to maximum 12 months

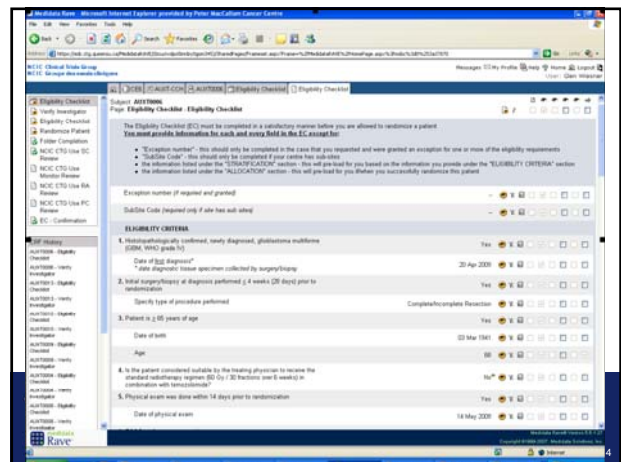


Stratification Centre
Age
ECOG
Extent of surgery (Biopsy vs more)

Sample size 560

Funding \$2000 per randomisation (Schering-Plough)

Participants NCIC open
EORTC open
TROG open
Select Japanese centres soon open



For TROG centres

Funding \$2000 per randomisation to centre (Schering-Plough)
\$200 to pathology service for each case

Pathology Diagnostic histopathology slides to NCIC
Tissue Banking
Second consent
TMA sample only to stay in Canada
Blocks returned (as default)



TROG-accrued patients n=16

| Age Group | n | Extent of surgery | | ECOG | |
|-----------|---|-------------------|-----------|------|---|
| | | Biopsy | Resection | 0-1 | 2 |
| 65-70 | 2 | 1 | 1 | 1 | 1 |
| 71-75 | 7 | 0 | 7 | 4 | 3 |
| >76 | 7 | 2 | 5 | 6 | 1 |



TROG accrued patients n=16

| ECOG | Extent of surgery | |
|-------|-------------------|-----------|
| | Biopsy | Resection |
| 0 - 1 | 1 | 10 |
| 2 | 2 | 3 |



7

Issues so far

- Accrual** Slower than expected in Canada
TROG started well but plateau
EORTC should speed things up
 - Daily running** Very few concerns (1 x minor violation)
EDC working well
Toxicity as expected from temozolamide
RT QA OK
 - Barriers** Celengitide competing (but 60Gy suitability differs)
Not all sites open
- Needs support from surgeons, med oncs and rad oncs



How to join or refer patients to site near you

Talk to us here!

email Claire Phillips or Mike Fay (TROG co-chairs)

TROG website
COGNO website

NEAF form available

