Wake Forest NCORP Research Base – Protocol 91105

Rapp SR, Case LD, Peiffer A, Naughton MM, Chan MD, Stieber VW, Moore DF, Falchuk SC, Piephoff JV, Edenfield WJ, Giguere JK, Loghin ME, and Shaw EG. Donepezil for irradiated brain tumor survivors: a phase III randomized placebo-controlled clinical trial. Journal of Clinical Oncology 33:1653-1659, 2015. PMID 25897156 NCT00369785

A total of 198 adult brain tumor survivors were randomly assigned to receive donepezil (5 mg for 6 weeks and 10 mg for 18 weeks) or placebo. Neurocognitive tests were assessed at baseline, 12 weeks post randomization, and 24 weeks post randomization. The primary aim of the study was to assess the effect of donepezil on a cognitive composite outcome (consisting of the average of eight standardized tests) at 24 weeks. A secondary aim was to assess the effect of donepezil on the individual tests. There was no significant effect of donepezil on the composite outcome. However, donepezil did significantly improve memory and motor speed/dexterity.

This dataset contains all the data used in the publication cited above. Note that in Table 1 of the paper, the percentages for Lung and Breast under Metastatic site should be 56% and 26% (instead of 57% and 27%) for the Donepezil group. Also note that in Table A1 of the paper, the number of white patients who completed treatment should be 134 (92%) instead of 90 (91%).

Baseline demographic and clinical variables are provided for time = 0 (baseline visit).

The primary outcome measures for the study are assessed at each time (0=baseline, 12=12 weeks, and 24=24 weeks).

Summary measures that are calculated across the participant's time on study (e.g., worst toxicities, compliance and completion status) are recorded on the time = 99 rows. Note that these are measures determined over the entire study period, not a specific time.

Notes: Missing data are denoted by a blank for each variable.

Data dictionary

Variable	Description	Type	Units	Values
Baseline Demographic and Clinical Information				
id	Participant Identifier	Classification		
group	Randomized arm	Classification		A=Donepezil B=Control
time	Visit	Classification		0=Baseline 12=12 weeks 24=24 weeks 99=Summary measures across the study period
age	Participant age	Number	years	
dx2reg	Time since diagnosis	Number	months	
bmi	Participant Body Mass Index	Number	kg/m^2	
strata	Stratification Factor – Combination of RT type and Primary vs CCOP site	Classification		1=WBI, WFU 2=WBI, CCOP 3=PBI, WFU 4=PBI, CCOP
ecog	Participant Eastern Cooperative Oncology Group Performance Status	Classification		0=Fully active, able to carry on all pre-disease performance without restriction 1=Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature. 2=Ambulatory and capable of all selfcare but unable to carry out any work activities. Up and about more than 50% of waking hours.
sex	Participant gender	Classification		F=Female M=Male
race	Participant race	Classification		A=Asian B=Black W=White

Variable	Description	Type	Units	Values
ethnic	Participant ethnicity	Classification		H=Hispanic N=Not Hispanic U=Unknown
raceethnic	Participant race/ethnicity	Classification		A=Asian (non-Hispanic or unknown) B=Black (non-Hispanic or unknown) H=Hispanic (White) W=White (non-Hispanic or unknown)
married	Participant marital status	Classification		1=Single 2=Married or married-like 3=Separated, divorced, or widowed
educ	Participant education level	Classification		1= High school graduate or less 2=Vocational or some college 3=College graduate or higher
income	Participant income status	Classification		1= < $20,000 2= $20,000-$50,000 3= ≥$50,000
work	Participant work outside home?	Classification		0=No 1=Yes
diagnosis	Participant diagnosis	Classification		1=Primary brain tumor 2=Brain metastasis 3=Prophylactic Cranial Irradiation (PCI)
primary_tumor_type	Type of brain tumor – for those with a primary brain tumor	Classification		1=Glioblastoma Multiforme 2=Anaplastic Astrocytoma 3=Anaplastic Oligodendroglioma 4=Anaplastic Oligoastrocytoma 5=Anaplastic Ependymoma 7=Anaplastic Mixed Glioma 8=Low-grade Astrocytoma 9=Low-grade Oligodendroglioma 10=Low-grade Oligastrocytoma 12=Meningioma 13=Pilocystic Astrocytoma 14=Other

Variable	Description	Type	Units	Values
met_site	Cancer site – for those with metastatic brain cancer or PCI	Classification		1=Lung 2=Breast 6=Other/Unknown
brain_vol	Brain volume	Number	cm^3	
csf_vol	CSF volume	Number	cm^3	
brain2icv	Brain or intracranial volume	Number	%	
lrvol_grp	Lesion or resection volume	Classification		0=0 1= <15 cm^3 2= ≥15 cm^3
hippo	Hippocampus Involvement	Classification		0=No 1=Yes
main_location	Primary location of brain involvement	Classification		2=Frontal 4=Parietal 5=Occipital 6=Temporal 7=Basal Ganglia 8=Cerebellum 9=Brainstem or Spinal Cord
hvlt_ir_std	HVLT immediate recall at baseline – standardized to a normal population	Number	SD units above or below the Reference Score	
hvlt_dr_std	HVLT – delayed recall at baseline – standardized to a normal population	Number	SD units above or below the Reference Score	
hvlt_sav_std	HVLT percent savings at baseline – standardized to a normal population	Number	SD units above or below the Reference Score	
hvlt_tp_std	HVLT recognition at baseline – standardized to a normal population	Number	SD units above or below the Reference Score	
hvlt_discrim_std	HVLT discrimination at baseline – standardized to a normal population	Number	SD units above or below the Reference Score	

Variable	Description	Type	Units	Values
cowa_std	COWA at baseline – standardized to a normal population	Number	SD units above or below the Reference Score	
dst_t_std	Digit Span (total of forward and backward) test at baseline – standardized to a normal population	Number	SD units above or below the Reference Score	
rocf_copy_std	ROCF copy test at baseline – standardized to a normal population	Number	SD units above or below the Reference Score	
rocf_ir_std	ROCF immediate recall test at baseline – standardized to a normal population	Number	SD units above or below the Reference Score	
rocf_dr_std	ROCF delayed recall test at baseline – standardized to a normal population	Number	SD units above or below the Reference Score	
tmt_a_std	Trail Making Test A at baseline – standardized to a normal population	Number	SD units above or below the Reference Score	
tmt_b_std	Trail Making Test B at baseline – standardized to a normal population	Number	SD units above or below the Reference Score	
gp_d_std	Grooved Pegboard Dominant Hand test at baseline – standardized to a normal population	Number	SD units above or below the Reference Score	
gp_nd_std	Grooved Pegboard Non-dominant Hand test at baseline – standardized to a normal population	Number	SD units above or below the Reference Score	
Cognitive Outcome Measures assessed at each time				

Variable	Description	Type	Units	Values
composite	Mean of HVLT immediate recall, HVLT delayed recall, ROCF delayed recall, DST total, COWA, TMT-A, TMT-B, and Grooved Pegboard dominant hand, each standardized using the pretreatment overall means and standard deviations. The negatives of TMT-A, TMT-B, and GP-D were used in calculating the composite score. In addition, log transformations were used for TMT-A and TMT-B before standardizing.	Number		
HVLTtotIR	HVLT immediate recall	Number	Score	0-36
HVLT_DR	HVLT – delayed recall	Number	Score	0-12
HVLTsav	HVLT percent savings	Number	%	≥0
HVLTrecogTP	HVLT recognition	Number	Score	0-12
HVLTdiscrim	HVLT discrimination	Number	Score	-12-12
COWAtot	COWA	Number	Score	≥0
DST_F	Digit Span forward	Number	Score	0-16
DST_B	Digit Span backward	Number	Score	0-14
DST_T	Digit Span (total of forward and backward)	Number	Score	0-30
ROCF_copy	ROCF copy	Number	Score	0-24
ROCF_IR	ROCF immediate recall	Number	Score	0-24
ROCF_DR	ROCF delayed recall	Number	Score	0-24
TMT_A	Trail Making Test A	Number	Seconds	0-300
TMT_B	Trail Making Test B	Number	Seconds	0-300
GP_D	Grooved Pegboard Dominant Hand	Number	Seconds	0-300
GP_ND	Grooved Pegboard Non-dominant Hand	Number	Seconds	0-300

Variable	Description	Type	Units	Values
Participant measures summarized across the study period				
nausea*	Worst nausea experienced by the participant over the course of the study.	Ordinal		0=None 1=Mild 2=Moderate 3=Severe 4=Life-threatening 5=Death
vomiting*	Worst vomiting experienced by the participant over the course of the study.	Ordinal		0 – 5
diarrhea*	Worst diarrhea experienced by the participant over the course of the study.	Ordinal		0 – 5
fatigue*	Worst fatigue experienced by the participant over the course of the study.	Ordinal		0 – 5
anorexia*	Worst anorexia experienced by the participant over the course of the study.	Ordinal		0 – 5
insomnia*	Worst insomnia experienced by the participant over the course of the study.	Ordinal		0 – 5
headache*	Worst headache experienced by the participant over the course of the study.	Ordinal		0 – 5
muscle_cramps*	Worst muscle cramps experienced by the participant over the course of the study.	Ordinal		0 – 5
pct_ideal**	Percentage of ideal dose over the course of the study.	Number		0-100
completed***	Did the participant complete the study	Classification		0=No 1=Yes

*Values for toxicities are based on the NCI Common Toxicity Criteria (CTC) 4.0

** pct_ideal is calculated as the percentage of recorded diary day for which the participant took the correct number of pills. For example, the participant was supposed to take 1 pill and actually took 1 pill they got 100% compliance for that day. If the participant was supposed to take two pills and took 0, 1, or more than 2 pills, they got 0% compliance for that day. This variable was not saved at the time of the analysis for the paper so is calculated on slightly updated data.

*** Note that one participant completed the study (i.e., on treatment and provided some data until week 24), but they did not complete the 24-week cognitive testing.