A Multi-Center, Randomized, Placebo-Controlled, Double-Blinded, Trial of Efficacy and Safety of Riluzole in Acute Spinal Cord Injury

Statistical Analysis

Contents

Study Overview

This was an international, multi-center, prospective, double-blinded, randomized, placebo- controlled Phase II/III clinical trial to evaluate if riluzole at a dose of 100 mg BID for the first 24 hours followed by 50 mg BID for 13 days was superior to placebo in subjects with acute traumatic spinal cord injury (SCI). The study utilized a randomization ratio of one riluzole subjectto one placebo subject (1:1). Additional trial information can be found by visiting ClinicalTrials.gov and searching for NCT01597518.

Study Objectives

Primary Objective

The primary objective was to evaluate the superiority of riluzole, at a dose of 100 mg BID the first 24 hours followed by 50 mg BID for the following 13 days after injury, as compared to placebo, in change between 180 days and baseline in motor outcomes as measured by International Standards for Neurological Classification of Spinal Cord Injury Examination (ISNCSCI) Motor Score, in patients with acute traumatic SCI, presenting to the hospital less than12 hours after injury.

Secondary Objectives

Secondary objectives were to evaluate the effects of riluzole on overall neurologic recovery, sensory recovery, functional outcomes, quality of life outcomes, health utilities, mortality, andadverse events.

Efficacy Endpoints

Primary Efficacy Endpoint

The primary efficacy endpoint was absolute change in International Standards for Neurological Classification of Spinal Cord Injury Examination (ISNCSCI) Total Motor Score (ISNCSCIMS)between 180 days and baseline.

Prior to any unblinding of the data from the study, the literature consensus emerged that the TotalMotor Score, which consists of Upper Motor Score and Lower Motor Score, is an unreliable measure. The current consensus is to use Upper Motor Score. With agreement from the DSMB statistician, the study has switched to Upper Motor Score for primary efficacy evaluation.

Secondary Efficacy Endpoints

The two secondary efficacy endpoints were:

- Change in ISNCSCI grade between baseline and 180 days, and
- Spinal Cord Independence Measure (SCIM) at 180 days

Other Endpoints

- Change in ISNCSCI Sensory Scores (Light Touch and Pin Prick) between 180 days andbaseline
- Change in ISNCSCI Upper Extremity Motor Score between 180 days and baseline(changed to Total Motor Score)
- Change in ISNCSCI Lower Extremity Motor Score between 180 days and baseline
- Change in Short Form 36 Version 2 (SF-36v2™) PCS, MCS and 8 dimensions between180 days and pre-injury (recall)
- Change in EQ-5D health utility between 180 days and pre-injury (recall)
- Graded Redefined Assessment of Strength Sensibility and Prehension (GRASSP) at 14days or Discharge (whichever occurred first) and 180 days
- Change in Numeric Pain Rating Scale (pain NRS) at 14 days, 84 days and 180 days

Selection of Study Population

Inclusion Criteria

- Age between 18 and 75 years inclusive
- Able to cooperate in the completion of a standardized neurological examination byISNCSCI standards (includes patients who are on a ventilator)
- Willing and able to comply with the study Protocol
- Signed Informed Consent Document (ICD) by patient, legal representative or witness
- Able to receive the Investigational Drug within 12 hours of injury
- ISNCSCI Impairment Scale Grade “A,” “B” or “C” based upon first ISNCSCI evaluationafter arrival to the hospital
- Neurological Level of Injury between C4-C8 based upon first ISNCSCI evaluation afterarrival to the hospital
- Women of childbearing potential must have a negative serum β-human chorionic gonadotropin (β-hCG) pregnancy test or a negative urine pregnancy test

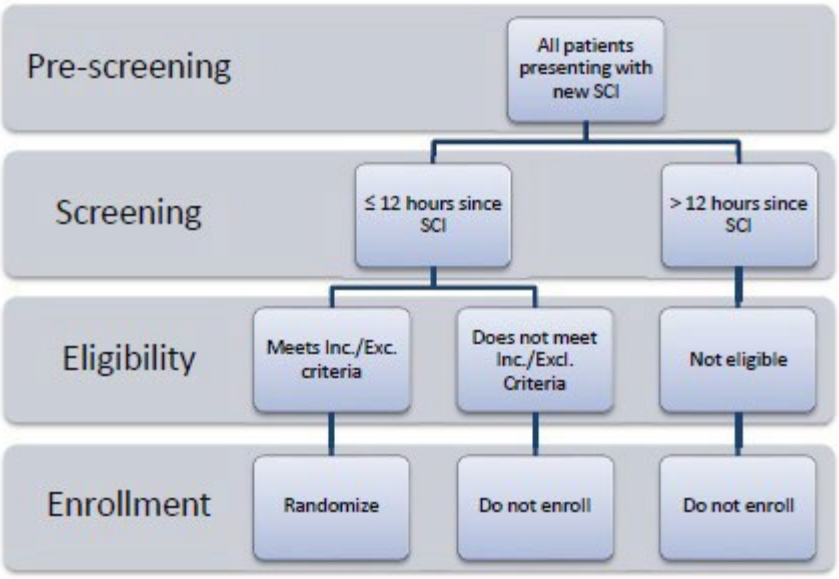
Exclusion Criteria

- Injury arising from penetrating mechanism
- Significant concomitant head injury defined by a Glasgow Coma Scale score < 14 with aclinically significant abnormality on a head CT (head CT required

only for patients suspected to have a brain injury at the discretion of the investigator)

- Pre-existent neurologic or mental disorder which would preclude accurate evaluation andfollow-up (i.e., Alzheimer's disease, Parkinson's disease, unstable psychiatric disorder with hallucinations and/or delusions or schizophrenia)
- Previous history of spinal cord injury
- Recent history (less than 1 year) of chemical substance dependency or significant psychosocial disturbance that may impact the outcome or study participation, in theopinion of the investigator
- Is a prisoner
- Participation in a clinical trial of another Investigational Drug or Investigational Devicewithin the past 30 days
- Hypersensitivity to riluzole or any of its components
- Neutropenia measured as absolute neutrophil count (ANC) measured in cells permicroliter of blood of < 1500 at screening visit
- Creatinine level of > 1.2 milligrams (mg) per deciliter (dL) in males or > 1.1 mg per dL infemales at screening visit
- Liver enzymes (ALT/SGPT or AST/SGOT) 3 times the upper limit of normal (ULN) atscreening visit
- Active liver disease or clinical jaundice
- Subject is currently using, and will continue to use for the next 14 days any of thefollowing medications which are classified as CYP1A2 inhibitors or inducers*:
    - <u>Inhibitors</u>:
        - Ciprofloxacin
        - Enoxacin
        - Fluvoxamine
        - Methoxsalen
        - Mexiletine
        - Oral contraceptives
        - Phenylpropanolamine
        - Thiabendazole
        - Zileuton
    - <u>Inducers</u>:
        - Montelukast
        - Phenytoin
- *Note: no washout period required; if these medications are discontinued, subjects areeligible to be enrolled in the trial
- Acquired immune deficiency syndrome (AIDS) or AIDS-related complex
- Active malignancy or history of invasive malignancy within the last five years, with the exception of superficial basal cell carcinoma or squamous cell carcinoma of the skin thathas been definitely treated. Patients with carcinoma in situ of the uterine cervix treated definitely more than 1 year prior to enrollment may enter the study

Screening and enrollment design



Safety Evaluation

Safety was monitored through the course of the study by a designated Independent Medical Safety Monitor (IMSM). Trends in serious adverse events (SAEs), laboratory events, and treatment-emergent adverse events (TEAEs) were reviewed by an external Data and Safety Monitoring Board (DSMB). The DSMB evaluated safety information against the pre-specifiedsafety stopping rules.

AEs were classified by body system and preferred term. Relative frequencies of AEs werecompared between the riluzole and placebo arms using chi-square test with alpha = 0.05.

Statistical Testing of Primary Endpoint

The appropriate statistical approach was to test a single one-sided null-hypothesis that the difference between the investigational and the placebo arm was equal to or less than 0. Rejectionof the null-hypothesis was consistent with superiority of the investigational treatment to the placebo.

Determination of Sample Size

The required sample size was 316 evaluable subjects, or 158 subjects per study arm.

The rationalefor the sample size is as follows.

The statistical analysis tested the null hypothesis of the superiority of riluzole compared to placebo in change of ISNCSCI Motor Score between the baseline and the 180-day follow-upvisits (change in ISNCSCIMS). See Table below.

The sample size was calculated to provide 90% power in testing the primary superiority hypothesis. The estimate was calculated by PROC SEQDESIGN for SAS/STAT. Standard deviation for the primary outcome parameter was made using the data from the STASCIS study(data on file with the Sponsor). This estimate was based on subjects with neurological level of injury from C4-C8 at arrival, the ISNCSCI Impairment grade "A," "B" or "C" and time from injury to arrival of less than 12 hours.

Endpoint	Standard Deviation
$\Delta ISNCSCIMS_{180\text{-}b}$	24.08

Study Success

The study was considered to successfully confirm the working hypothesis if H_0 for the primaryendpoint was rejected either at interim or the final analysis.

Study success was defined as follows: Investigational treatment (riluzole) was superior to placebo. Study success was achieved if the one-sided null hypothesis of no superiority of riluzolegroup in change in $ISNCSCIMS_{180\text{-}b}$ was rejected.

Preplanned Subgroup Analysis

A pre-planned sub-group analysis was conducted to evaluate differences in change in $ISNCSCIMS_{180\text{-}b}$ among the patients in baseline ISNCSCI Impairment Groups "A," "B" and "C."The rationale for this pre-planned analysis was that these groups experience different recovery ofISNCSCIMS which may result in between-group differences in change in $ISNCSCIMS_{180\text{-}b}$.

Motor recovery, as measured by change in ISNCSCIMS between acute admission and 6 months follow-up, is known to vary according to individuals' baseline level of injury severity, as definedby ISNCSCI grade. The variability in motor recovery depending on the baseline injury severity has been fully incorporated into the sample size estimate calculations. At present, the data from the Phase I study of riluzole in SCI are under analysis. Such data, when available, will be incorporated in the planning of this sub-group analysis. However, this pre-planned sub-group analysis is of interest from an

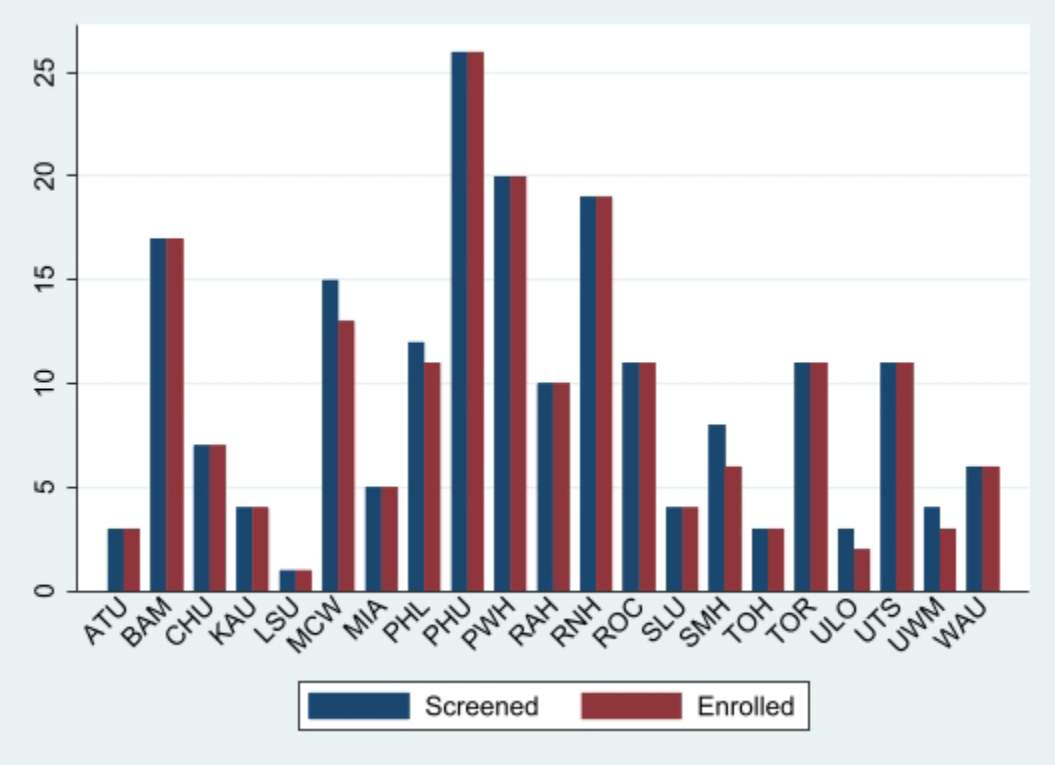
exploratory perspective and will be used for purposes of planning future studies which may serve to further refine riluzole's role in the treatment of SCI. Statisticaldetails of this analysis was provided in the SAP.

RESULTS

Termination of Study

Due to the COVID-19 pandemic, screening & enrollment to the RISCIS trial was suspended by the Sponsor (AOSpine North America/AOSNA) on May 1, 2020. At that time, 193 subjects had been enrolled to the study.

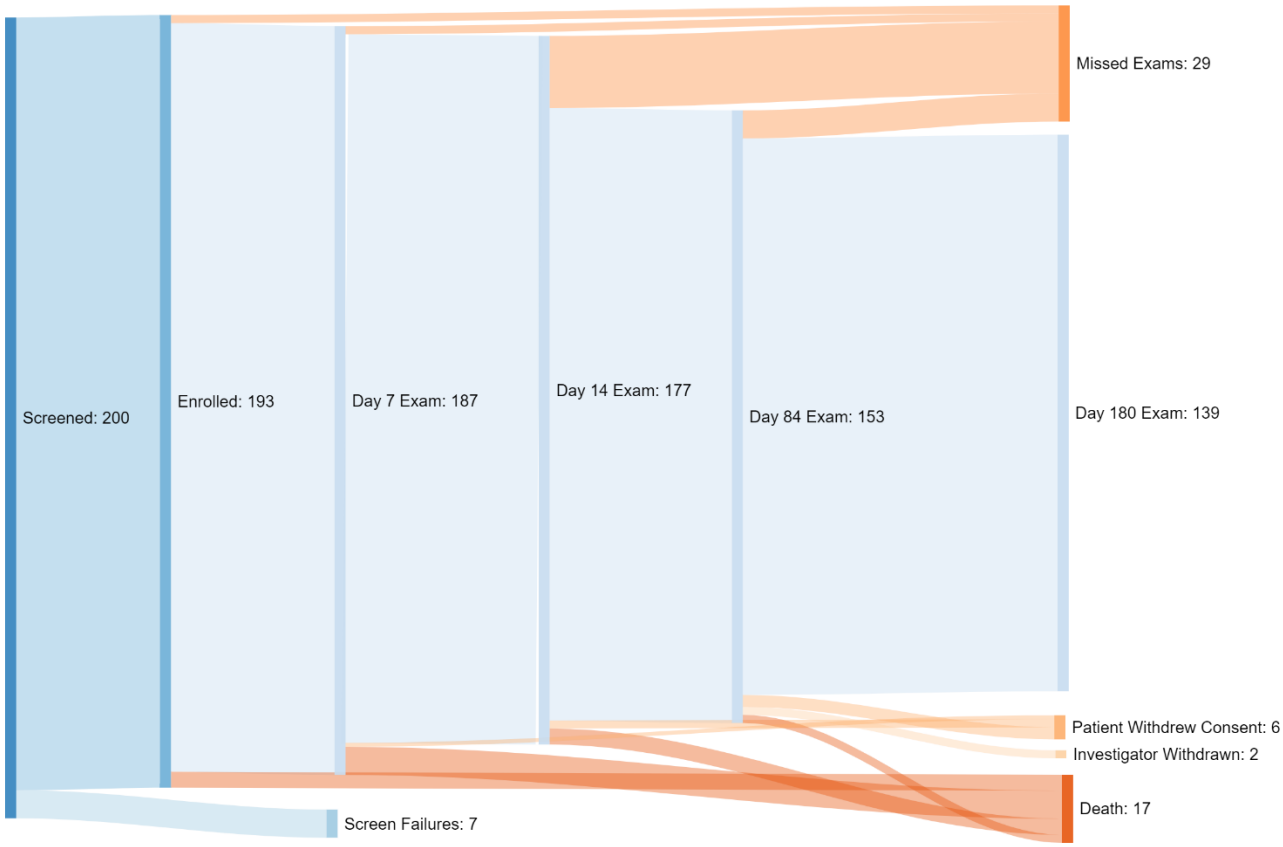
Screening and Enrollment Per Site



Subject Accounting

The follow-up rate at 180-day visit was 82.70% and at 365-day the follow-up rate was 82.40% . The follow-up rate was similar between Riluzole and Placebo groups. At the 180-dayfollow-up, 69 of 81 (85.19%) of the expected Riluzole subjects and 70 of 87 (80.46%) of the expected placebo subjects attended the visit.

	Enrollment	72 hour	7 day	14 day	84 day	180 day	365 day
Treated	193	193	193	193	193	193	193
Enrolled	193	193	193	193	193	193	193
Ineligible (Excluded for major protocol violation)	32	32	32	32	32	32	32
Not yet due	0	0	0	0	0	0	0
Theoretical	193	193	193	193	193	193	193
Not yet overdue	0	0	0	0	0	0	0
Ineligible for F/U (Investigator-withdrawn)	0	0	0	0	0	2	5
Ineligible for F/U (Patient self-withdrawn)	0	0	0	1	3	6	10
Ineligible for F/U (Death)	0	0	4	11	15	17	19
Expected	193	193	189	181	175	168	159
Actual (Complete in window)	189	139	181	167	124	97	102
Actual (Any Data)	193	193	187	177	153	139	131
% Follow-up (Complete in window)	97.90%	72.00%	95.80%	92.30%	70.90%	57.70%	64.20%
% Follow-up (Any Data)	100.00%	100.00%	98.90%	97.80%	87.40%	82.70%	82.40%



Demographic and Other Baseline Characteristics

In the Treatment group, the mean age was 49.4 years (SD=17.1, range 19-74 years) with a mean Body Mass Index (BMI)of 28.8 (range 17-59). There were 17 females and 79 males.

In the Control group the mean age was 47.6 years (SD=16.0, range 20-74 years) with a meanBody Mass Index (BMI) of 28.4 (range 19-51). There were 18 females and 79 males.

	Riluzole (N=96)	Control (N=97)	Riluzole - Control	P-value
Age at consent (years) [1]				
n	96	97		0.453
Mean	49.4	47.6	1.8	
SD	17.1	16.0		
95% CI			-2.9 - 6.5	
Median	51	50		
Range	19 - 74	20 - 74		

Gender, n (%) [2]				
Male	79 (82.3)	79 (81.4)		1.000
Female	17 (17.7)	18 (18.6)		
Height (cm) [1]				
n	92	90		0.733
Mean	175.5	175.0	0.5	
SD	8.6	10.1		
95% CI			-2.3 - 3.2	
Median	177	177		
Range	150 - 193	151 - 205		
Weight (kg) [1]				
n	90	89		0.682
Mean	88.4	87.2	1.3	
SD	20.8	20.6		
95% CI			-4.8 - 7.4	
Median	86	83		
Range	45 - 191	50 - 166		
Body mass index [1]				
n	86	84		0.675
Mean	28.8	28.4	0.4	
SD	6.0	5.8		
95% CI			-1.4 - 2.2	
Median	28	27		
Range	17 - 59	19 - 51		
Race, n(%) [2]				
White	69 (71.9)	71 (73.2)		0.496
Black or African American	13 (13.5)	15 (15.5)		
Asian	10 (10.4)	7 (7.2)		
Native Hawaiian or other Pacific Islander	1 (1.0)	0		
American Indian or Native American	1 (1.0)	0		
Other	1 (1.0)	4 (4.1)		
Subject did not answer	1 (1.0)	0		
Ethnicity, n(%) [2]				
Hispanic or Latino	2 (2.1)	3 (3.1)		1.000

Not Hispanic or Latino	92 (95.8)	92 (94.8)		
Unknown	2 (2.1)	1 (1.0)		
Subject did not answer	0	1 (1.0)		

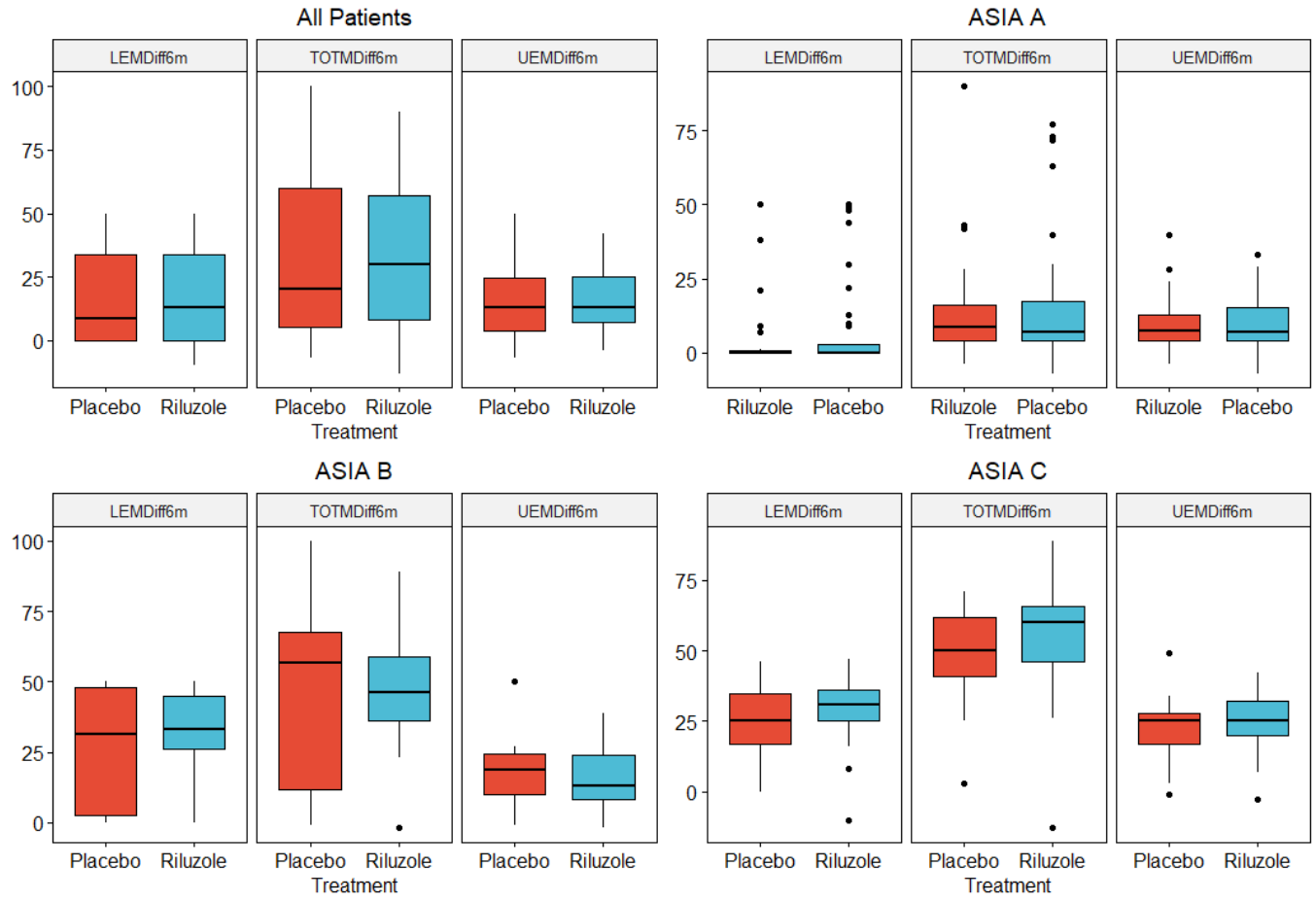
Summary of Injury Characteristics

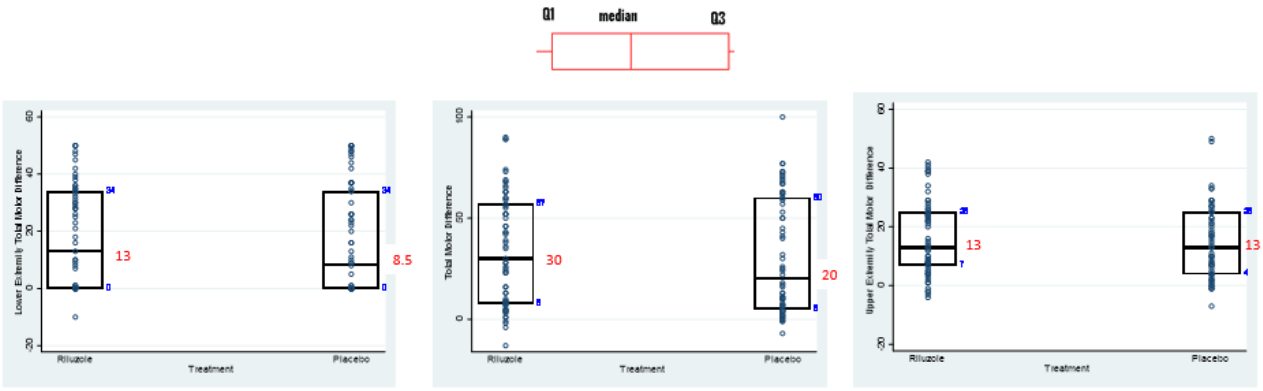
	N	Mean (Std. Dev)
Age (years)	193	48.47 (16.49)
ISNCSCI		
Motor Score Total	189	17.44 (13.01)
Motor Score Upper Total	190	13.33 (10.66)
Motor Score Lower Total	191	4.07 (7.96)
	N	**%**
Gender		
Female	35	18.13%
Male	158	81.87%
ASIA Impairment Scale		
A	101	52.33%
B	38	19.69%
C	52	26.94%
D	1	0.52%
Not Done	1	0.52%
Neurologic Level		
C3	2	1.04%
C4	104	53.89%
C5	49	25.39%
C6	22	11.40%
C7	10	5.18%
C8	1	0.52%
T2	1	0.52%
Not Done	4	2.07%

Primary Outcomes

Summary Plot of Outcomes

Please refer to R Code BLOCK 1 for the codes to generate the following graphs





LE Motor Score | Total Motor Score | Upper Extremity Motor Score

Primary Statistical Testing of Motor Outcomes

Please refer to R Code BLOCK 2 for the codes to generate the following table

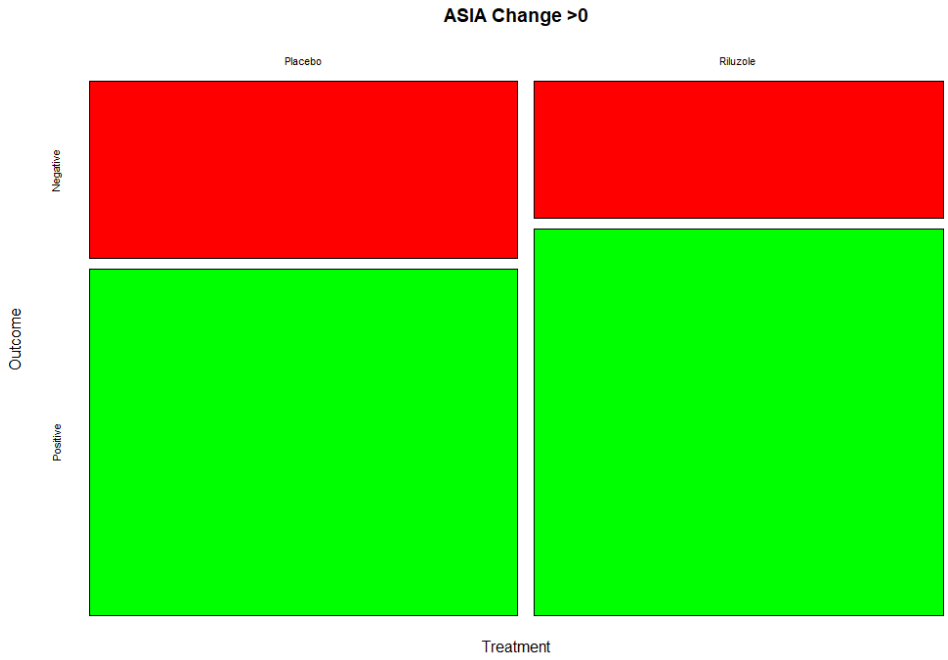
Two sample, one-tailed T-test with null hypothesis that the difference in outcomes at 6 months is the same between placebo and Riluzole group. Alternative hypothesis is that the difference in the Riluzole group is greater.

	Placebo (mean)	**Riluzole (mean)**	**P-Value**
Change in Upper Extremity Motor Scores at 6 Months	14.65	16.42	0.7907
Change in Lower Extremity Motor Scores at 6 Months	16.10	17.55	0.6767
Change in Total Motor Scores at 6 Months	31.11	34.00	0.7209

SECONDARY OUTCOMES

ASIA Difference at 6 months

CODE BLOCK 3




```
Comparing : Placebo vs. Riluzole

         Negative Positive    P(Negative) 95% conf. interval
Placebo        23       45         0.3382    0.2362   0.4579
Riluzole       17       48         0.2615    0.1692   0.3811

                                  95% conf. interval
            Relative Risk: 1.2933    0.7637   2.1899
        Sample Odds Ratio: 1.4431    0.6836   3.0467
Conditional MLE Odds Ratio: 1.4391    0.6414   3.2775
    Probability difference: 0.0767   -0.0787   0.2262

            Exact P-value: 0.3515
       Asymptotic P-value: 0.3360
```

Neurological Level Change at 6 Months

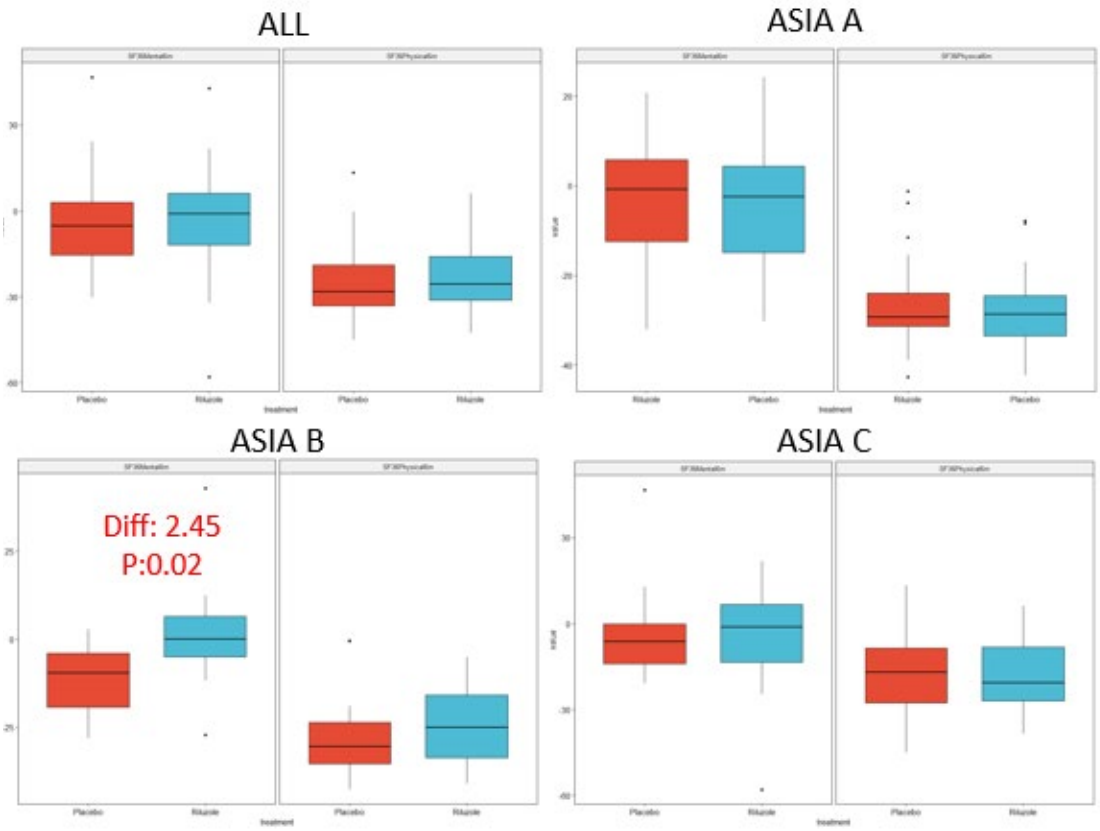
Code Block 4

```
data:  data$NLIDiff6m by Treatment
t = -0.40467, df = 120.04, p-value = 0.6568
alternative hypothesis: true difference in means is greater than 0
95 percent confidence interval:
 -1.056972       Inf
sample estimates:
 mean in group Placebo mean in group Riluzole
             0.5303030              0.7377049
```


```
Comparing : Placebo vs. Riluzole

         Negative Positive    P(Negative) 95% conf. interval
Placebo        23       45         0.3382    0.2362   0.4579
Riluzole       17       48         0.2615    0.1692   0.3811

                                  95% conf. interval
            Relative Risk: 1.2933    0.7637   2.1899
          Sample Odds Ratio: 1.4431    0.6836   3.0467
Conditional MLE Odds Ratio: 1.4391    0.6414   3.2775
    Probability difference: 0.0767   -0.0787   0.2262

             Exact P-value: 0.3515
        Asymptotic P-value: 0.3360
------------------------------------------------------
```

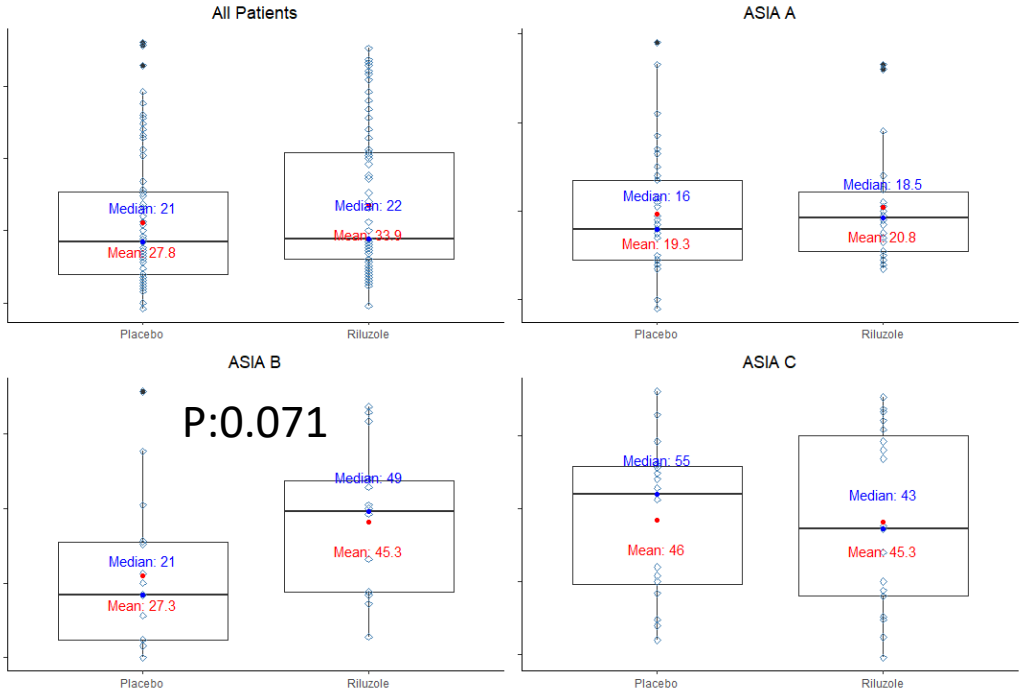
SF36 Change at 6 months

Code Block 5



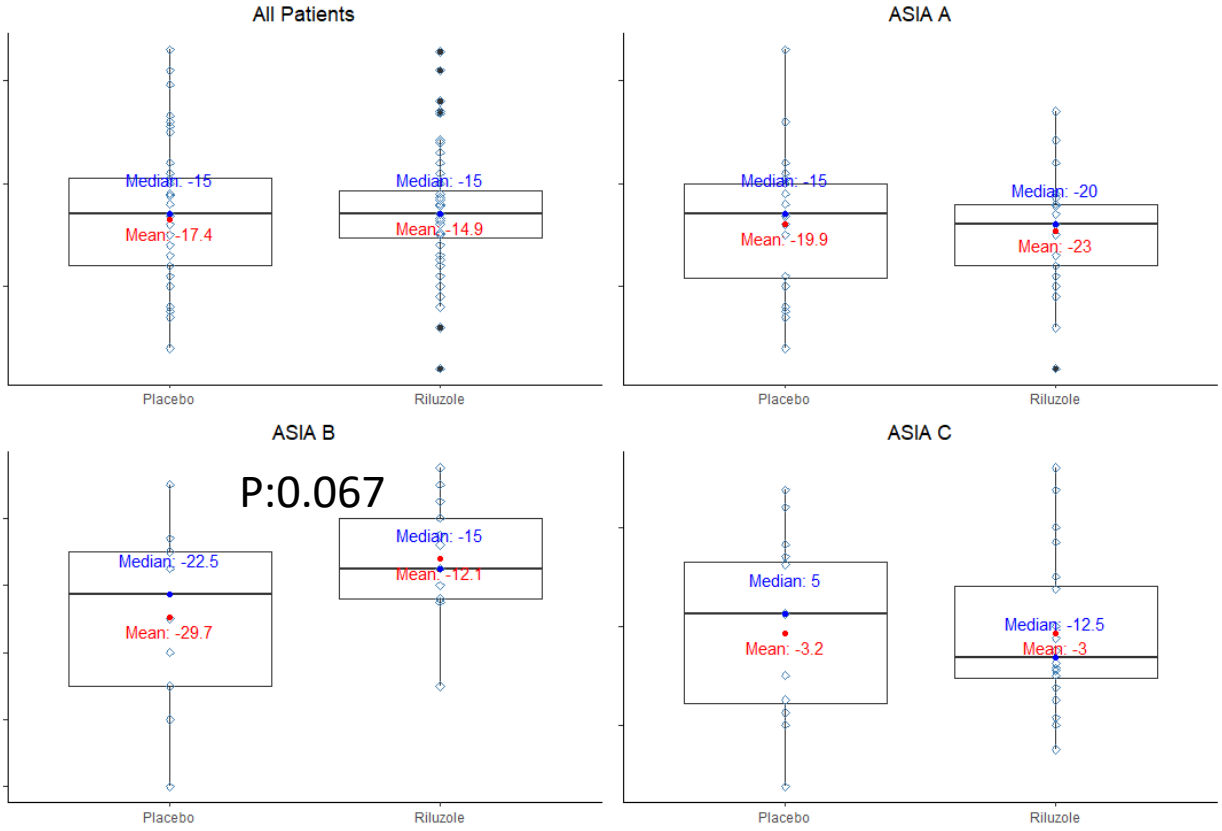
SCIM Score Change at 6 Months

Code Block 6



VAS Score Change 6 Months

Code Block 7



Multivariate Models

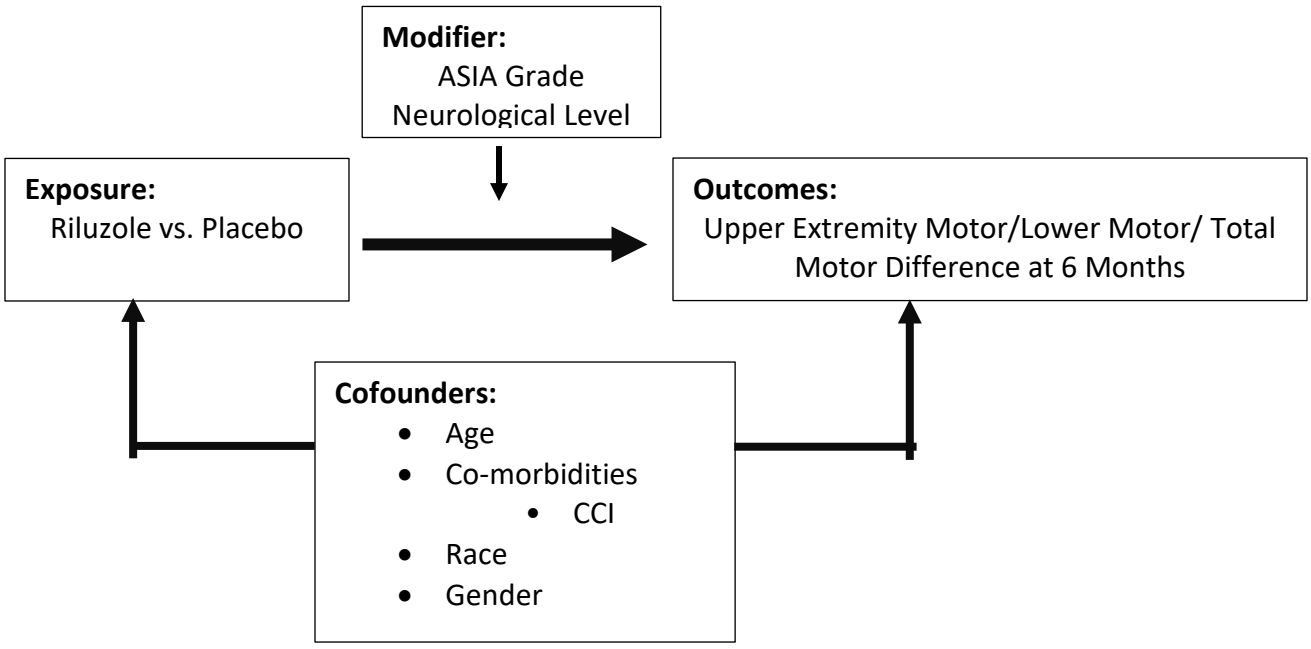
Variable Selection

All the available variables in the data base were examined a-priori for selection based on clinical relevance. Below is a table of the variables available for selection

Variable	Selected (Y/N)	Explanation
Age	Y	Age has been shown to be a significant predictor of outcomes in other studies
Weight/Height/BMI	N	No studies have been isolated body habitus as a predictor of outcomes in SCI
Comorbidities	Y	Numerous co-morbidities were recorded. It established that comorbidity conditions, particularly in the frail elderly are associated with changes in outcomes in SCI. We decided to use the Charlson Comorbidity Index which was primary recorded in the trial. The CCI is a numeric grade that takes into account 16 different comorbidities.
Gender	Y	
Race	Y	
Ethnicity	N	Given that Race was already included we decided not to include ethnicity
Neurological Level	Y	
ASIA Grade	Y	

Note after graphing the variable Age with the outcome variables no obvious division was found for splines

Conceptual Model



Types of Models

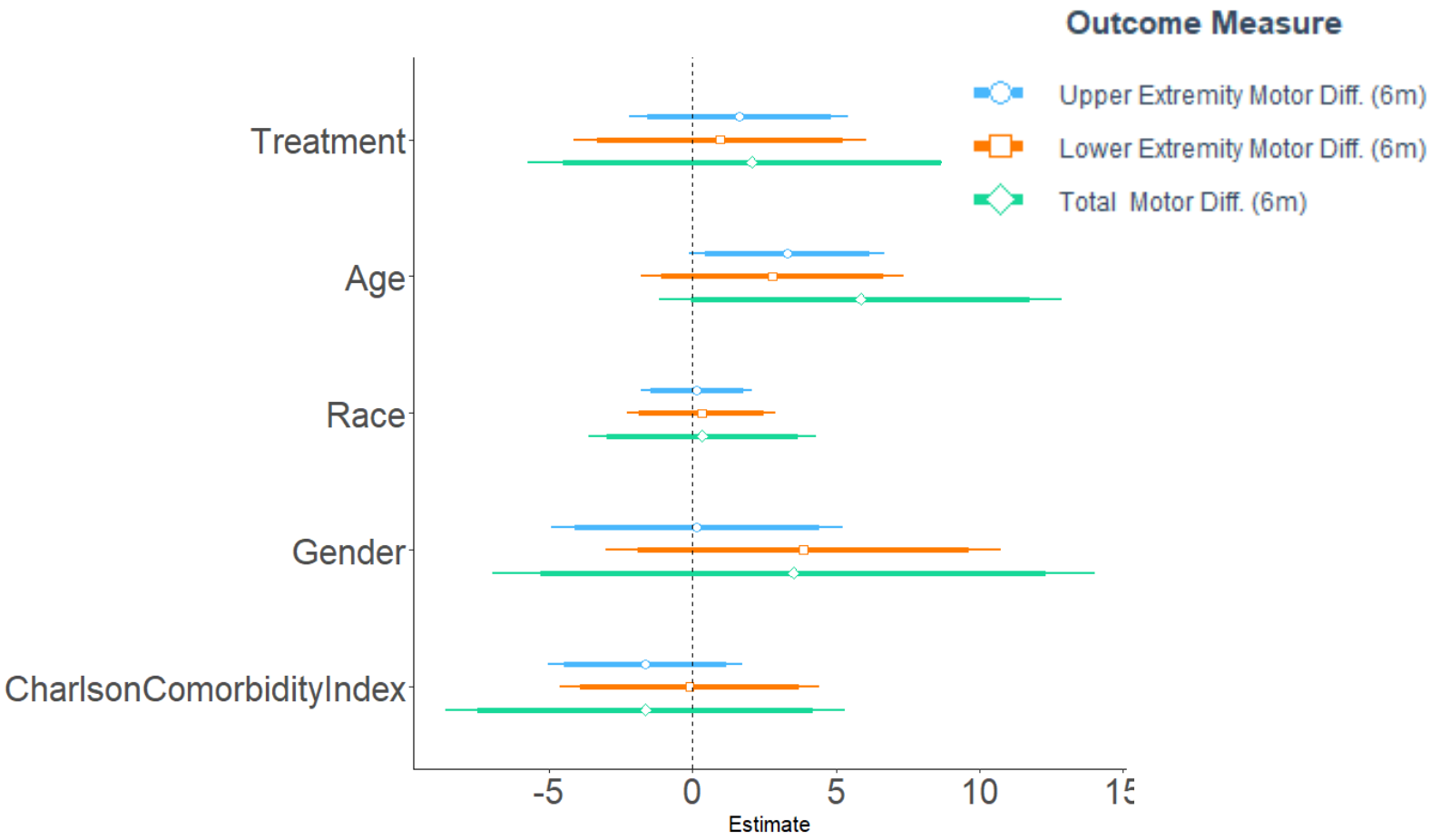
Two types of models were selected.

1) A mixed effect model with the random effects being the ASIA grade and Neurological level was fitted on all date.

2) A separate Multivariate Linear Regression model was then fitted for each ASIA Grade.

Linear Mixed Effect Model

Code Block 8



	Upper Extremity Motor Diff. (6m)	Lower Extremity Motor Diff. (6m)	Total Motor Diff. (6m)
(Intercept)	8.97	6.64	18.40
	[-3.85, 21.79]	[-10.55, 23.83]	[-7.90, 44.70]
TreatmentRiluzole	1.62	0.96	2.07
	[-2.19, 5.42]	[-4.15, 6.07]	[-5.76, 9.90]
Age	0.20	0.17	0.36
	[-0.01, 0.42]	[-0.11, 0.46]	[-0.07, 0.80]
Race	0.13	0.29	0.32
	[-1.68, 1.94]	[-2.14, 2.73]	[-3.42, 4.05]
Gender	0.15	3.86	3.52
	[-4.93, 5.23]	[-3.02, 10.74]	[-6.98, 14.02]
CharlsonComorbidityIndex	-1.29	-0.09	-1.29
	[-3.94, 1.36]	[-3.66, 3.49]	[-6.74, 4.16]
N	128	130	128
N (NeurologicalLevel)	7	7	7
N (BaselineASIA)	4	4	4
AIC	980.33	1070.30	1156.31
BIC	1006.00	1096.11	1181.97
R2 (fixed)	0.03	0.03	0.03
R2 (total)	0.37	0.37	0.37

Linear Models

Code Block 9

All Patients

	Upper Extremity Motor Diff. (6m)	Lower Extremity Motor Diff. (6m)	Total Motor Diff. (6m)
(Intercept)	11.81	-14.27	-2.92
	[-2.03, 25.65]	[-34.59, 6.06]	[-34.02, 28.18]
Age	0.29 *	0.43 *	0.72 **
	[0.07, 0.52]	[0.09, 0.76]	[0.21, 1.23]
Race	0.09	-0.20	-0.01
	[-1.92, 2.10]	[-3.15, 2.74]	[-4.52, 4.50]
Gender	2.36	6.72	8.82
	[-3.19, 7.91]	[-1.46, 14.89]	[-3.66, 21.29]
CharlsonComorbidityIndex	-1.37	-1.83	-3.20
	[-4.24, 1.51]	[-6.06, 2.41]	[-9.65, 3.25]
NeurologicalLevel	-2.70 *	1.06	-1.41
	[-4.86, -0.53]	[-2.07, 4.19]	[-6.28, 3.46]
TreatmentRiluzole	3.10	2.70	5.45
	[-1.08, 7.27]	[-3.42, 8.81]	[-3.93, 14.82]
N	128	130	128
AIC	1003.89	1120.77	1211.13
BIC	1026.70	1143.71	1233.95
Pseudo R2	0.14	0.12	0.13

*** p < 0.001; ** p < 0.01; * p < 0.05

ASIA A

	Upper Extremity Motor Diff. (6m)	Lower Extremity Motor Diff. (6m)	Total Motor Diff. (6m)
(Intercept)	6.48	-2.91	3.33
	[-11.06, 24.01]	[-26.88, 21.07]	[-34.89, 41.55]
TreatmentRiluzole	0.19	-4.05	-3.90
	[-4.74, 5.12]	[-10.87, 2.77]	[-14.64, 6.84]
Age	0.17	0.25	0.42
	[-0.09, 0.43]	[-0.11, 0.62]	[-0.15, 0.99]
Race	-0.79	-2.01	-2.78
	[-3.00, 1.42]	[-5.06, 1.03]	[-7.60, 2.04]
Gender	3.42	2.83	6.21
	[-4.37, 11.20]	[-8.00, 13.65]	[-10.76, 23.17]
CharlsonComorbidityIndex	-0.70	0.75	0.05
	[-4.16, 2.75]	[-4.06, 5.57]	[-7.48, 7.58]
NeurologicalLevel	-1.26	-0.11	-1.31
	[-4.04, 1.52]	[-3.76, 3.55]	[-7.37, 4.75]
N	63	64	63
AIC	473.90	523.68	572.06
BIC	491.05	540.95	589.20
Pseudo R2	0.08	0.18	0.15

ASIA B

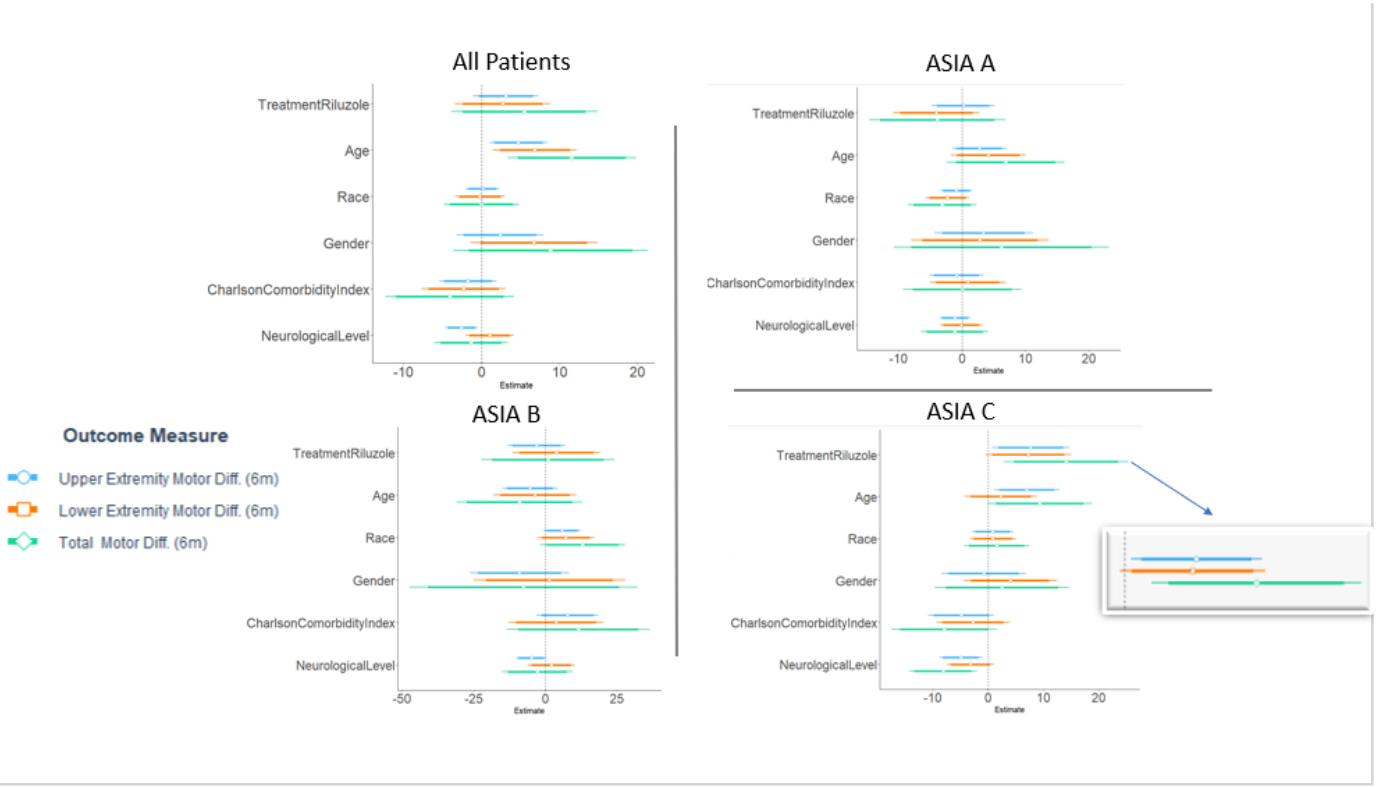
	Upper Extremity Motor Diff. (6m)	Lower Extremity Motor Diff. (6m)	Total Motor Diff. (6m)
(Intercept)	6.48	-2.91	3.33
	[-11.06, 24.01]	[-26.88, 21.07]	[-34.89, 41.55]
TreatmentRiluzole	0.19	-4.05	-3.90
	[-4.74, 5.12]	[-10.87, 2.77]	[-14.64, 6.84]
Age	0.17	0.25	0.42
	[-0.09, 0.43]	[-0.11, 0.62]	[-0.15, 0.99]
Race	-0.79	-2.01	-2.78
	[-3.00, 1.42]	[-5.06, 1.03]	[-7.60, 2.04]
Gender	3.42	2.83	6.21
	[-4.37, 11.20]	[-8.00, 13.65]	[-10.76, 23.17]
CharlsonComorbidityIndex	-0.70	0.75	0.05
	[-4.16, 2.75]	[-4.06, 5.57]	[-7.48, 7.58]
NeurologicalLevel	-1.26	-0.11	-1.31
	[-4.04, 1.52]	[-3.76, 3.55]	[-7.37, 4.75]
N	63	64	63
AIC	473.90	523.68	572.06
BIC	491.05	540.95	589.20
Pseudo R2	0.08	0.18	0.15

*** p < 0.001; ** p < 0.01; * p < 0.05.

ASIA C

	Upper Extremity Motor Diff. (6m)	Lower Extremity Motor Diff. (6m)	Total Motor Diff. (6m)
(Intercept)	24.69	29.11 *	55.61 **
	[0.76, 48.62]	[2.48, 55.75]	[17.41, 93.80]
TreatmentRiluzole	7.68 *	7.28	14.10 *
	[0.66, 14.69]	[-0.48, 15.04]	[2.89, 25.30]
Age	0.50 *	0.16	0.67
	[0.07, 0.92]	[-0.31, 0.64]	[-0.01, 1.34]
Race	0.88	0.92	1.67
	[-3.17, 4.93]	[-3.60, 5.44]	[-4.79, 8.13]
Gender	-0.80	3.97	2.49
	[-8.40, 6.79]	[-4.47, 12.41]	[-9.63, 14.62]
CharlsonComorbidityIndex	-3.47	-1.96	-5.64
	[-7.70, 0.76]	[-6.69, 2.76]	[-12.39, 1.12]
NeurologicalLevel	-5.92 *	-3.90	-9.79 *
	[-10.54, -1.31]	[-9.05, 1.26]	[-17.16, -2.42]
N	37	38	37
AIC	284.36	300.29	318.96
BIC	297.24	313.39	331.85
Pseudo R2	0.29	0.15	0.29

Graphs of All Linear Models

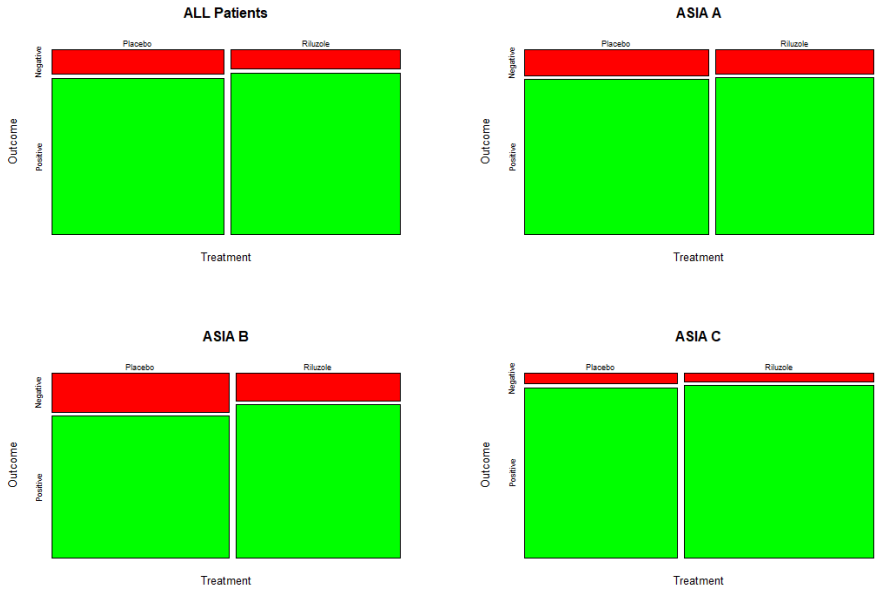


Binary/MCID Results

While a MCID is not fully established in the literature, it is generally accepted that 5 points in the Total Motor and 2 points in the Upper/Lower motor aggregates can be viewed to represent MCID. In this section we dichotomize outcomes based on the MCID Cutoff

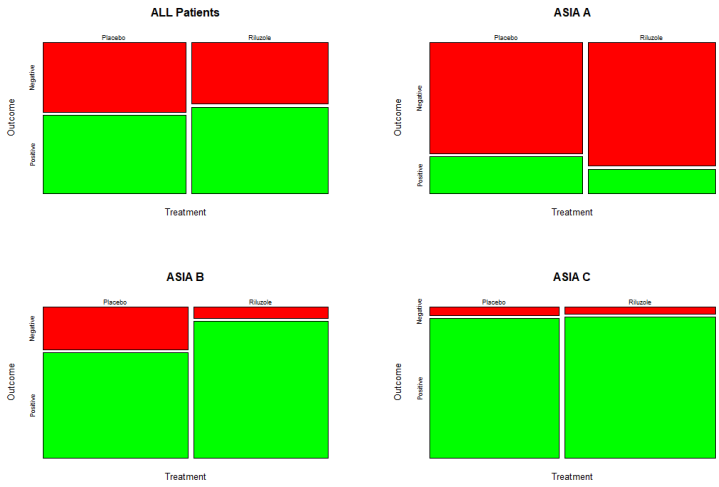
Code Block 10

UEM



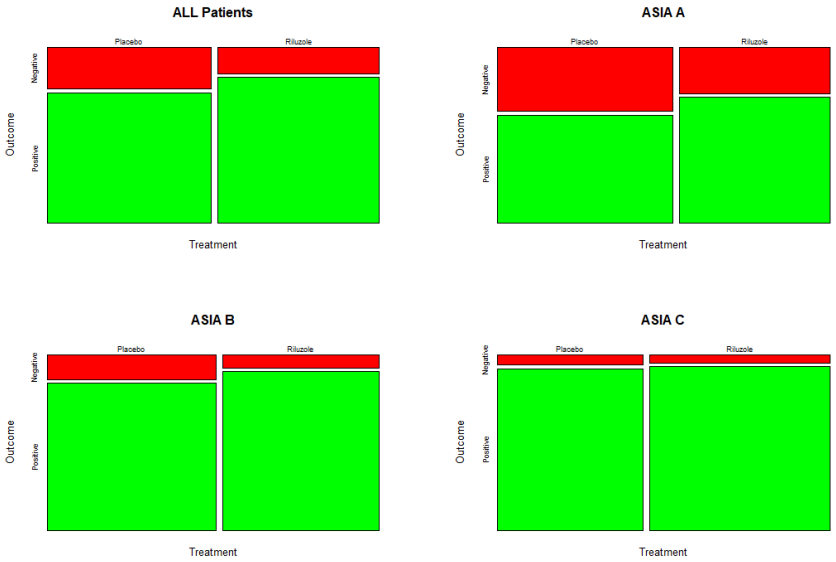
Non reach significance (alpha: 0.05)

LEM



Non reach significance (alpha: 0.05)

Total Motor



Non reach significance (alpha: 0.05)

Summary of all Results

Legend

Effect Towards Riluzole

* Statistical Significance

Univariate

	All	ASIA A	ASIA B	ASIA C
Upper Extremity Motor Change (6months)				
Lower Extremity Motor Change (6months)				
Total Motor Change (6months)				

Multi Variate

	Mixed Effect	ALL	ASIA A	ASIA B	ASIA C
Upper Extremity Motor Change (6months)					
Lower Extremity Motor Change (6months)					
Total Motor Change (6months)					

Binary

	All	ASIA A	ASIA B	ASIA C
Upper Extremity Motor Change (6months)				
Lower Extremity Motor Change (6months)				
Total Motor Change (6months)				

Secondary Outcomes

6 Month Improvement	ALL	ASIA A	ASIA B	ASIA C
SF36 Physical Score				
SF36 Mental Score				
SCIM				
EQ5D VAS Score				