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NCT02238626

Novel Composite Endpoint Extended Analysis During Extension of Ibudilast Phase 1b / 2a Clinical Trial Better Predicts Post-Wash-Out Survival

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Disclosures

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Joanna Dojillo MS is an employee of MediciNova

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Ibudilast - Glial Pathology MS, ALS, Glioblastoma Treatment Development

Ibudilast Pharmacology - Target Engagement

Adaptive Protocol - Early Cohort (EC) - DB - OLE -12 months
- Vital Status post Ibudilast Washout

CONSORT Diagram - DB - OLE -12 months

Adaptive Protocol - Loss of Muscle Strength off Ibudilast

Adaptive Protocol - Novel Composite Endpoint

Adaptive Protocol - Relation of Novel Composite Endpoint to Survival

Adaptive Protocol - Relation of Per Protocol Completion to Survival

Conclusions - Multiple Myeloma Stem Cell Therapy ALS Gene Therapy ALS

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Ibudilast - Glial Pathology

MS, ALS, Glioblastoma

Treatment Development

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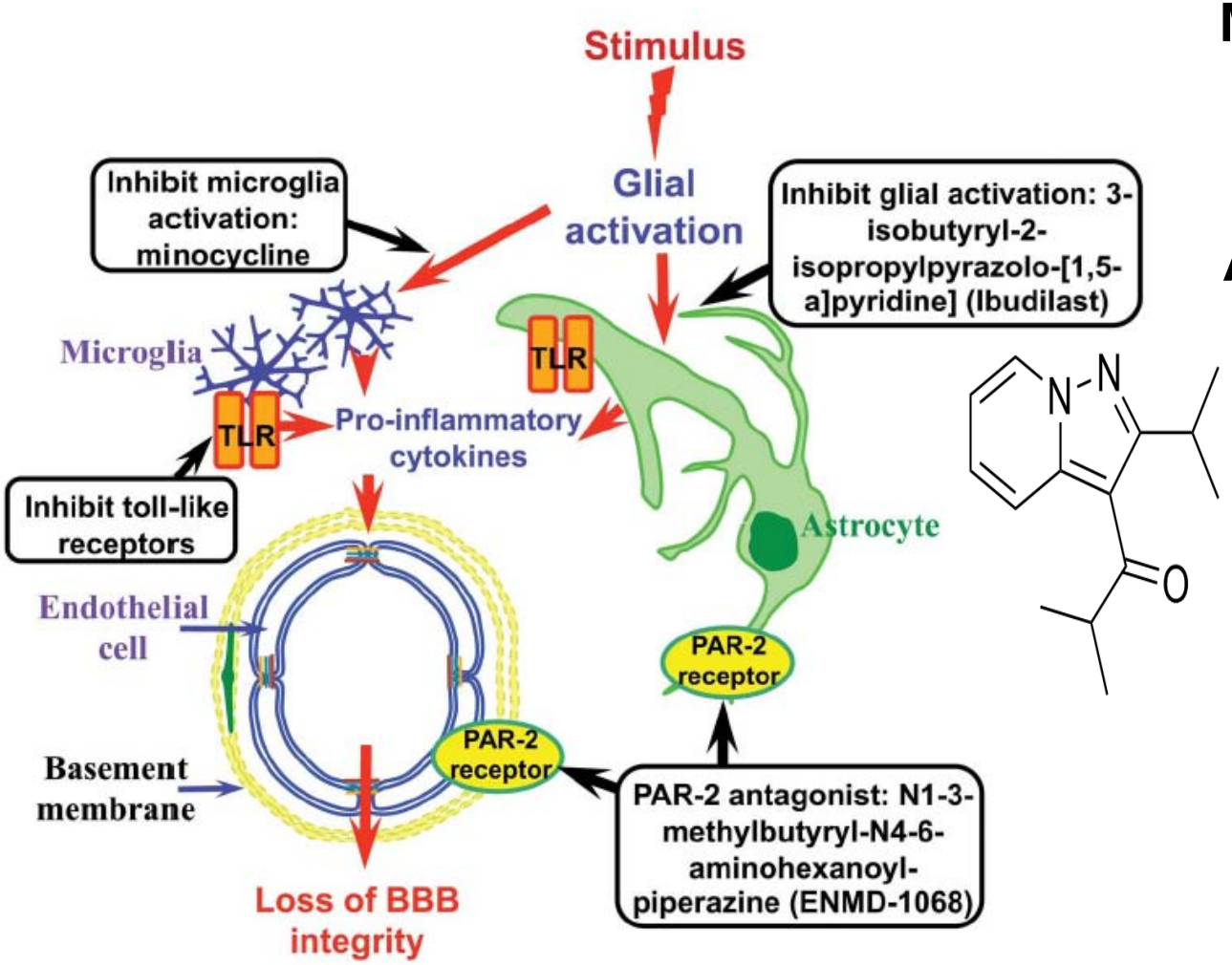

MS

NN102 SPRINT-MS

SPRINT-MS

ALS

U.S. National Library of Medicine
ClinicalTrials.gov

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Ibudilast (MN-166) in Subjects With Amyotrophic Lateral Sclerosis (ALS) (IBU-ALS-1201)

This study is ongoing, but not recruiting participants.

Sponsor:
MediciNova

ClinicalTrials.gov Identifier:
NCT02238626

First Posted: September 12, 2014
Last Update Posted: October 20, 2017

U.S. National Library of Medicine
ClinicalTrials.gov

MGH

A Biomarker Study to Evaluate MN-166 (Ibudilast) in Subjects With Amyotrophic Literal Sclerosis (ALS)

This study is currently recruiting participants.
See Contacts and Locations
Verified August 2017 by MediciNova

Sponsor:
MediciNova

ClinicalTrials.gov Identifier:
NCT02714036

First Posted: March 21, 2016
Last Update Posted: August 14, 2017

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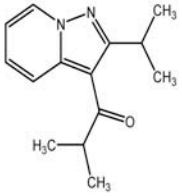
MSPARIS2017
7TH JOINT ECTRIMS – ACTRIMS MEETING
25–28 OCTOBER 2017, PARIS, FRANCE

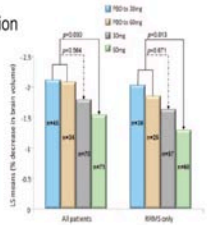
SPRINT-MS/NN 102 Phase II Trial of Ibudilast in Progressive MS: Top-Line Results

R.J. Fox, C.S. Coffey, M.E. Cudkowicz, T. Gleason, A. Goodman, E.C. Klawiter, K. Matsuda, M. McGovern, R. Conwit, R. Naismith, A. Ashokkumar, D. Eckund, E. Klinger, M. Koepp, S. Natarajan, B. Thornell, J. Yankey, R.A. Bermel, X. Huang, M.J. Lowe, K. Nakamura, S. Narayanan, K.E. Sakaie, J.P. Debbins, X. Zhou, E. Alvarez, M. Apperson, K. Bashir, B. Cohen, P. Coyle, S. Delgado, D. Dewitt, A. Flores, B. Giesser, M. Goldman, B. Jubelt, N. Lava, S. Lynch, H. Moses, D. Ontaneda, J. Perumal, M. Racke, P. Repovic, C. Riley, C. Severson, S. Shinnar, V. Suski, B. Weinstock Guttman, V. Yadav, A. Zabeti

Ibudilast (MN-166, AV411)

- Orally-available small molecule
  - Macrophage migration inhibitor factor (MIF) inhibitor
  - Phosphodiesterase (PDE)-4 and PDE-10 inhibitor
  - Toll-like receptor 4 inhibitor
- Approved in Japan in 1989
  - Bronchial asthma
  - Post-stroke dizziness
- Reduces atrophy progression and black hole formation in RRMS
- Animal models suggest neuroprotection:
  - Krabbe's disease
  - Spinal cord injury
  - Traumatic brain injury
  - Chronic neuropathic pain
  - Cerebral aneurysm



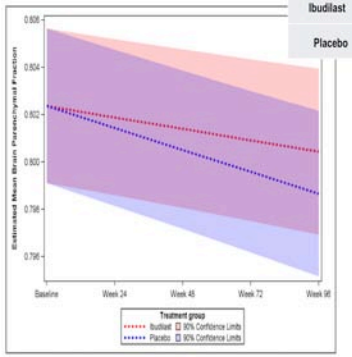


Barkhof et al, Neurol 2010

Brain Atrophy Is Clinically Relevant During Disease Progression

Primary Objective 1: BPF

Estimated Rate of Annual BPF Change		
Treatment Group	Estimate (90% CI)	P-Value
Ibudilast	-0.00105 (-0.00160, -0.00049)	0.040
Placebo	-0.00202 (-0.00256, -0.00147)	



Primary results show significant difference in slope of BPF over time.

Treatment with ibudilast was associated with a 48% slowing in rate of decline.

29th international symposium on ALS/MND Glasgow

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J Neurooncol (2016) 127:427–434
DOI 10.1007/s11060-016-2080-6

TOPIC REVIEW

The challenges associated with molecular targeted therapies for glioblastoma

Toni Rose Jue[1] · Kerrie L. McDonald[1]

Received: 30 September 2015 / Accepted: 15 February 2016 / Published online: 22 February 2016

Abstract Glioblastoma (GBM) is the most aggressive malignant brain tumor in adults. Improvements in the treatment of GBM have remained static since the advent of the standard therapy which includes radiation with concurrent and adjuvant temozolomide treatment. Developing treatment and diagnostic or companion biomarker combinations is transforming the way we treat numerous cancers. However, can this emerging paradigm be also effective for GBM? Can GBM be treated the same way as other cancers? Here we review the challenges for a personalized molecular targeted therapeutic approach in GBM. The specific challenges for establishing a personalized molecular targeted medicine program for GBM patients include overcoming the blood brain barrier, unravelling the intra- and inter-heterogeneity that exists and the importance of developing more relevant animal models that recapitulate a patient's GBM tumor.

5 years. GBM are highly refractory to treatment with local tumor recurrence occurring 2–3 cm from the original resection cavity (the area exposed to radiation treatment) frequently observed. Relapsed GBMs are difficult to manage with a median survival of only a few months after recurrence [1]. Increasingly, the development of novel therapies involve defining drug-diagnostic combinations where the presence of a molecular target or marker identifies patients who are most likely to respond to a specific therapy. This model of developing treatment and diagnostic/companion biomarker combinations is the emerging paradigm for novel drug and diagnostic development [2–4] with a recent example being the use of BRAF inhibitors, which target a specific activating mutation of BRAF (V600E) in melanoma [5]. GBM is characterized by inter- and intra-patient genomic and histopathological diversity, arising from the complex dynamics that underpin its development. Given this, a single "bullet" approach is unrealistic.

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Neuro-Oncology

SNOLA

P01.20 Treatment of recurrent glioblastoma with the cytokine inhibitor, ibudilast in combination with temozolomide

K. L. McDonald, W. Ha, M. Khasraw

Neuro-Oncology, Volume 19, Issue suppl_3, 1 May 2017, Pages iii27,
https://doi.org/10.1093/neuonc/nox036.096
Published: 19 April 2017

Cite Permissions Share

Abstract

BACKGROUND: Recurrence in patients with glioblastoma (GBM) is inevitable, even in patients with *O-6-Methylguanine-DNA Methyl Transferase* (*MGMT*) methylation. We identified increased expression of the inflammatory cytokine, Macrophage Inhibitory Factor (MIF) and its receptor CD74 in patients with recurrent tumours. High levels of MIF and CD74 were associated with poor overall survival in GBM patients. This study aims to determine efficacy of Ibudliast (AV411; 3-isobutyryl-2-isopropylpyrazolo-[1,5-a]pyridine) to block MIF expression and decrease tumour burden. Ibudilast is an anti-inflammatory drug that was developed for the treatment of bronchial asthma.

METHODS: The patient derived cell lines (PDCLs) RN1 (*MGMT* unmethylated), BAH1 (*MGMT* methylated), and HW1 (*MGMT* methylated) were treated *in vitro* with different concentrations of ibudilast in combination with temozolomide (TMZ). Patient derived xenograft (PDX) models of GBM were developed and treated with the combination of

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NCI Designated Comprehensive Cancer Center — Dana-Farber/Harvard Cancer Center
NCCN National Comprehensive Cancer Network®

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Ibudilast Pharmacology

Target Engagement

NCT02238626 Background

Riluzole Pharmacology

Riluzole currently slows the rate of loss of ALSFRS-R by 25-28% when administered at 50mg-twice-daily to achieve levels of 30-1552 ng/mL corresponding to 0.15-6.6 µM (Groeneveld, 2003).

Tissue levels are 10-fold higher (Milane, 2009) providing *in vivo* levels that permit multiple pharmacological activities including

CREB-mediated enhancement of neurotrophic factors (Tsuchioka, 2011)

CREB-mediated glutamate transport activation (Hayashida, 2010)

Riluzole has weak phosphodiesterase (PDE) inhibitor activity (Duprat, 2000).

NCT02238626 Background

Enhance Riluzole Pharmacology

Both riluzole and some PDE inhibitors reduce infarct size following transient cerebral artery occlusion (O'Neill, 1997).

Ibudilast, achieves this reduced infarct size at serum levels achievable in humans (Lee, 2011).

Decreased Cytokine Production by Microglia

Reduction in TNFalpha production by activated microglia (Kiebala, 2011, Hama,2012) and astroctyes (Yoshikawa, 2002).

Inhibition Matrix Metalloproteinase-9

Inhibition of matrix metallo-proteinase-9 (Yagi, 2010) which may be a key factor in ALS progression (Kaplan, 2014).

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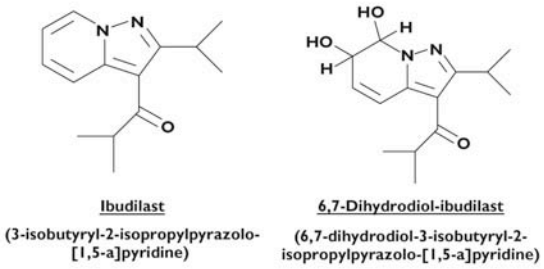
Ibudilast Pharmacology - Target Engagement

Ibudilast Biochemistry IC_{50}

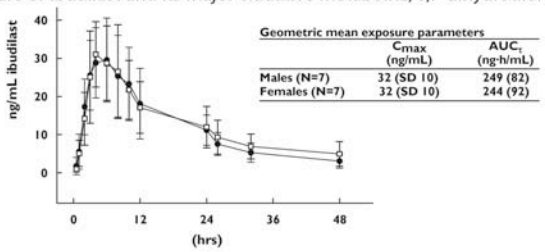
PDE4A - 0.05 µM
PDE4B - 0.06 µM
PDE4C - 0.24 µM
PDE4D - 0.17 µM



Ibudilast
(3-isobutyryl-2-isopropylpyrazolo-[1,5-a]pyridine)

6,7-Dihydrodiol-ibudilast
(6,7-dihydrodiol-3-isobutyryl-2-isopropylpyrazolo-[1,5-a]pyridine)

Figure 1
Chemical structure of ibudilast and its major oxidative metabolite, 6,7-dihydrodiol-ibudilast



Geometric mean exposure parameters

	C_{max} (ng/mL)	AUC_t (ng·h/mL)
Males (N=7)	32 (SD 10)	249 (82)
Females (N=7)	32 (SD 10)	244 (92)

Chronic daily oral administration of Ibudilast at 30mg twice-daily in humans can achieve peak [0.25 µM] and trough [0.15 µM] serum levels (Yoon, 2009). Brain and spinal cord levels of Ibudilast are higher (Sanftner, 2009).

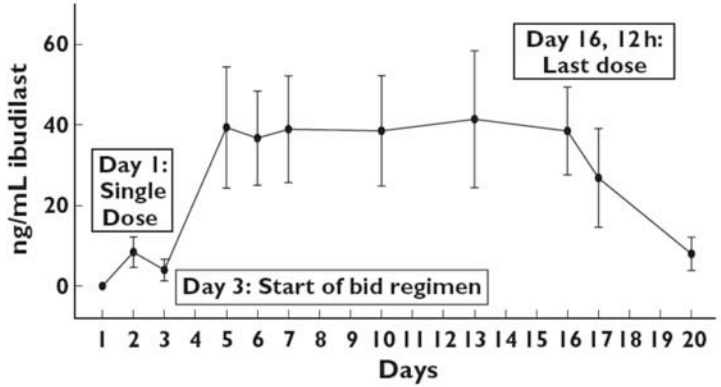


Figure 3
Mean trough plasma concentrations of ibudilast. Trough ibudilast plasma concentrations from $n = 14$ subjects receiving a 30-mg single administration on day 1, followed by $n = 10$ subjects receiving 30 mg b.i.d. from day 3 to day 16. Data represents mean (± SD)

Ibudilast Pharmacology

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Adaptive Protocol

- Early Cohort (EC)

- DB - OLE -12 months

- Vital Status post Ibudilast Washout

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Methods

Inclusion/Exclusion Criteria

Inclusion:

- Age 18-80 years
- Diagnosis of familial or sporadic ALS
- ALS with onset of ≤ 5 yrs for EC
- SVC ≥ 60%
- Currently on stable dose of Riluzole

Exclusion:

- Use of Tracheostomy, invasive mechanical ventilation, Non-invasive ventilation NIV
- > 3% predicted loss in post-diagnosis VC per month or
- > 1 unit loss in post diagnosis ALSFRS-R total score per month

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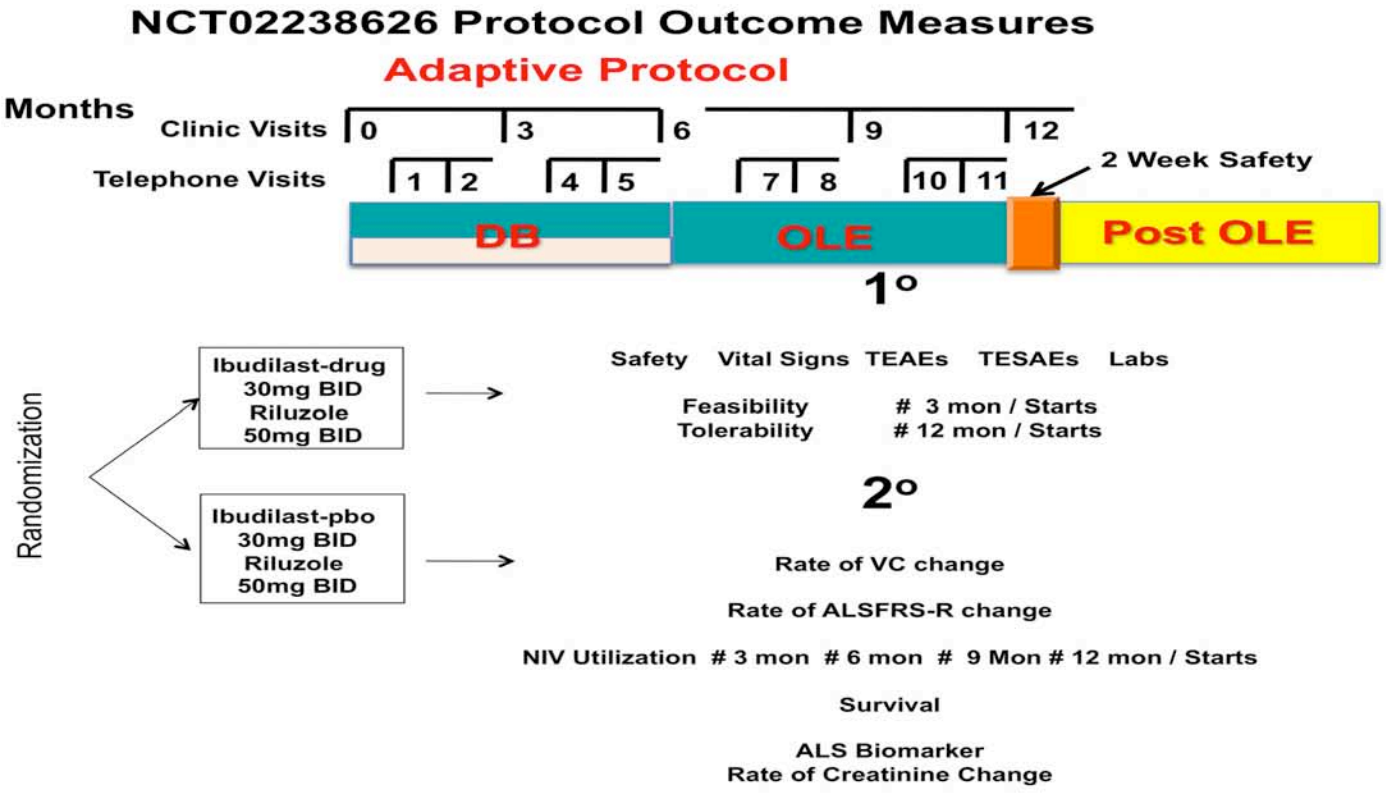
Methods

MN-166-ALS-1201 Adaptive Design Protocol



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Baseline Characteristics

	Placebo (N=17)	Ibudilast (N=34)
Age	57.5	59.2
Female	5 (29.4%)	11 (32.4%)
Ethnicity		
•Caucasian	15 (88.2%)	31 (91.2%)
•African American	2 (11.8%)	1 (2.9%)
•Asian	0%	1 (2.9%)
•Unknown	0%	1 (2.9%)
Baseline ALSFRS-R	39.0	39.3
Baseline SVC	97.2	92.0
Baseline MIP/NIF	-98.1	-86.0
Baseline MMT (Right)	4.08	4.16
Baseline MMT (Left)	3.97	4.15
Baseline ALSQ-5	6.4	6.4

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CONSORT Diagram DB - OLE -12 months

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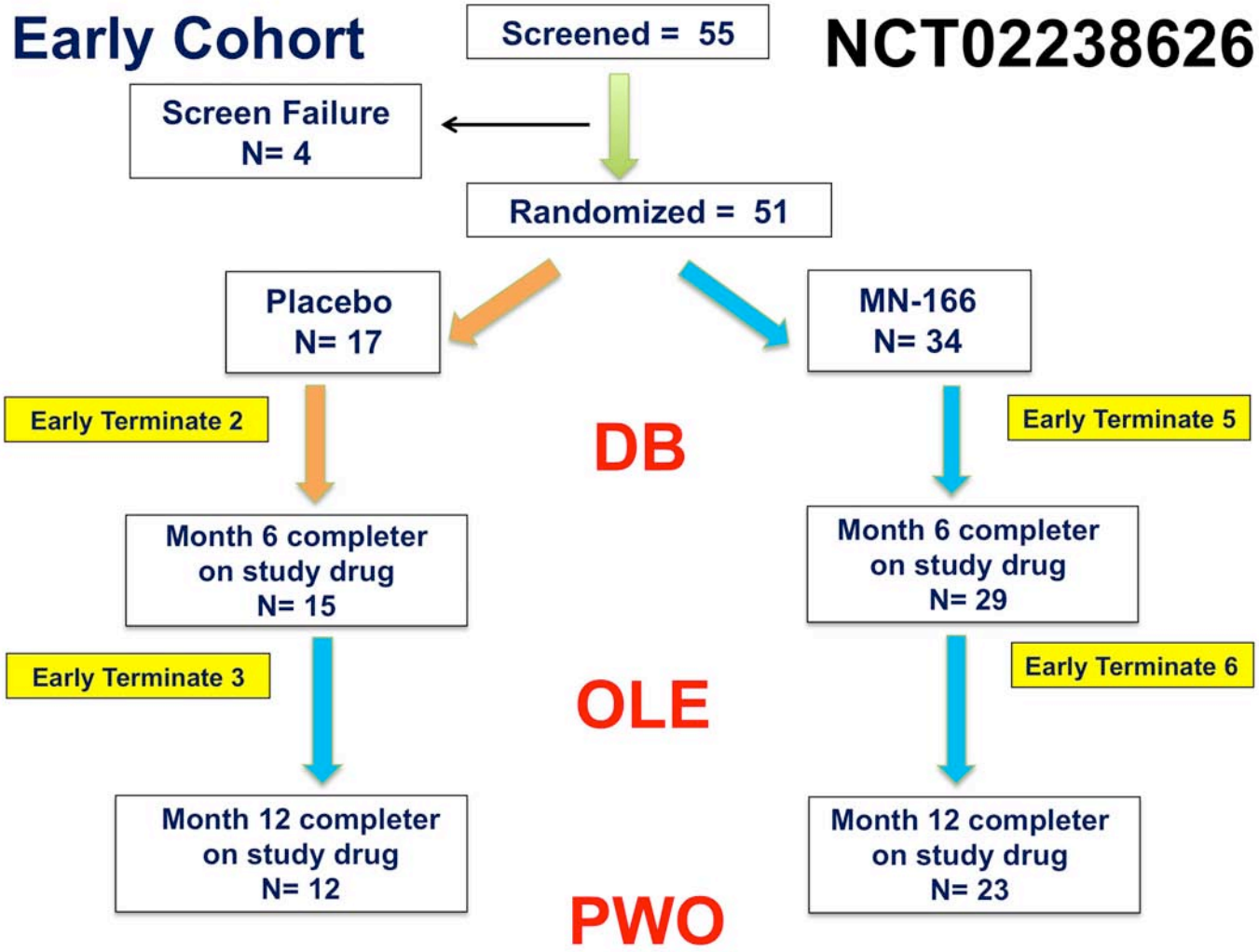
CONSORT Subject Trajectories



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Adaptive Protocol

Loss of Muscle Strength off Ibudilast

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Decreased Strength off Ibudilast

Statistically Significant Decrease in Neck Flexion
2 Weeks post Stopping Ibudilast

MN-166-ALS-1201 Mon 12 + 2 Weeks

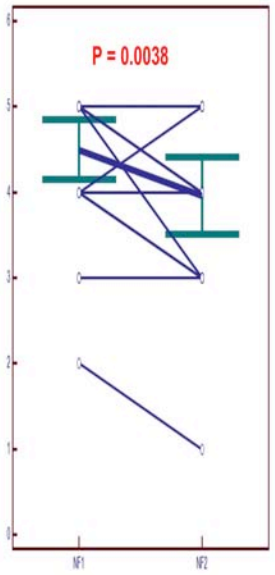
Bulbar (N=9) & Limb (N=17)
Neck Flexion

Paired samples t-test

	Sample 1	Sample 2
Sample size	25	25
Arithmetic mean	4.5200	3.8615
95% CI for the mean	4.1525 to 4.8875	3.5720 to 4.4110
Variance	0.7400	1.0385
Standard deviation	0.8602	1.1123
Standard error of the mean	0.1687	0.2183

Paired samples t-test

Mean difference	-0.6585
Standard deviation of mean difference	0.8521
Standard error of mean difference	0.1666
95% CI	-0.9958 to -0.1914
Test statistic t	-3.185
Degrees of Freedom (DF)	25
Two-tailed probability	P = 0.0038



Statistically Significant Decrease in Hip Flexion
2 Weeks post Stopping Ibudilast

MN-166-ALS-1201 Mon 12 + 2 Weeks

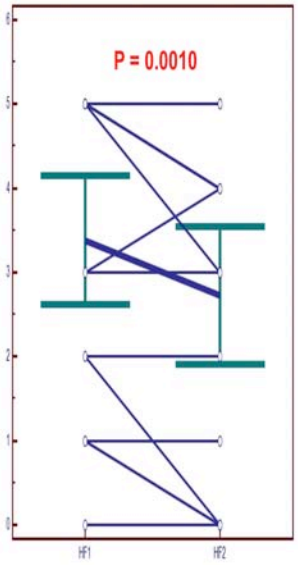
Bulbar (N=9) & Limb (N=17)
Hip Flexion

Paired samples t-test

	Sample 1	Sample 2
Sample size	25	25
Arithmetic mean	3.3640	2.7308
95% CI for the mean	2.8176 to 4.1516	1.9195 to 3.5511
Variance	1.9092	4.1048
Standard deviation	1.3569	2.0259
Standard error of the mean	0.2714	0.4051

Paired samples t-test

Mean difference	-0.6538
Standard deviation of mean difference	0.8618
Standard error of mean difference	0.1748
95% CI	-1.0141 to -0.2936
Test statistic t	-3.738
Degrees of Freedom (DF)	25
Two-tailed probability	P = 0.0010



Statistically Significant Decrease in Leg Flexion
2 Weeks post Stopping Ibudilast

MN-166-ALS-1201 Mon 12 + 2 Weeks

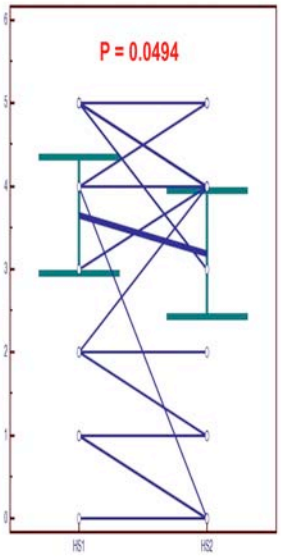
Bulbar (N=9) & Limb (N=17)
Hamstrings

Paired samples t-test

	Sample 1	Sample 2
Sample size	25	25
Arithmetic mean	3.6538	3.1923
95% CI for the mean	2.8501 to 4.4574	2.4043 to 3.9803
Variance	3.0254	3.7215
Standard deviation	1.7392	1.9288
Standard error of the mean	0.3477	0.3858

Paired samples t-test

Mean difference	-0.4615
Standard deviation of mean difference	1.1385
Standard error of mean difference	0.2277
95% CI	-0.9319 to 0.0090
Test statistic t	-2.026
Degrees of Freedom (DF)	25
Two-tailed probability	P = 0.0494



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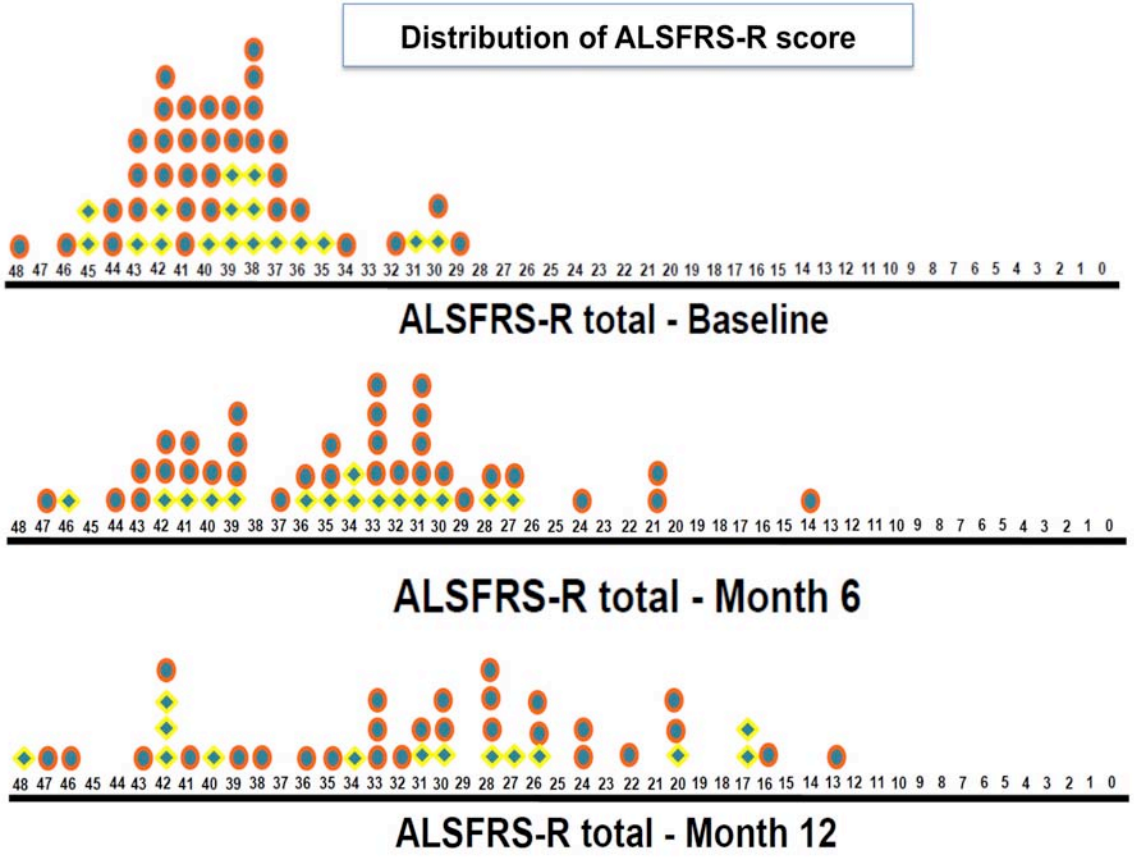
ALSFRS-R Responders



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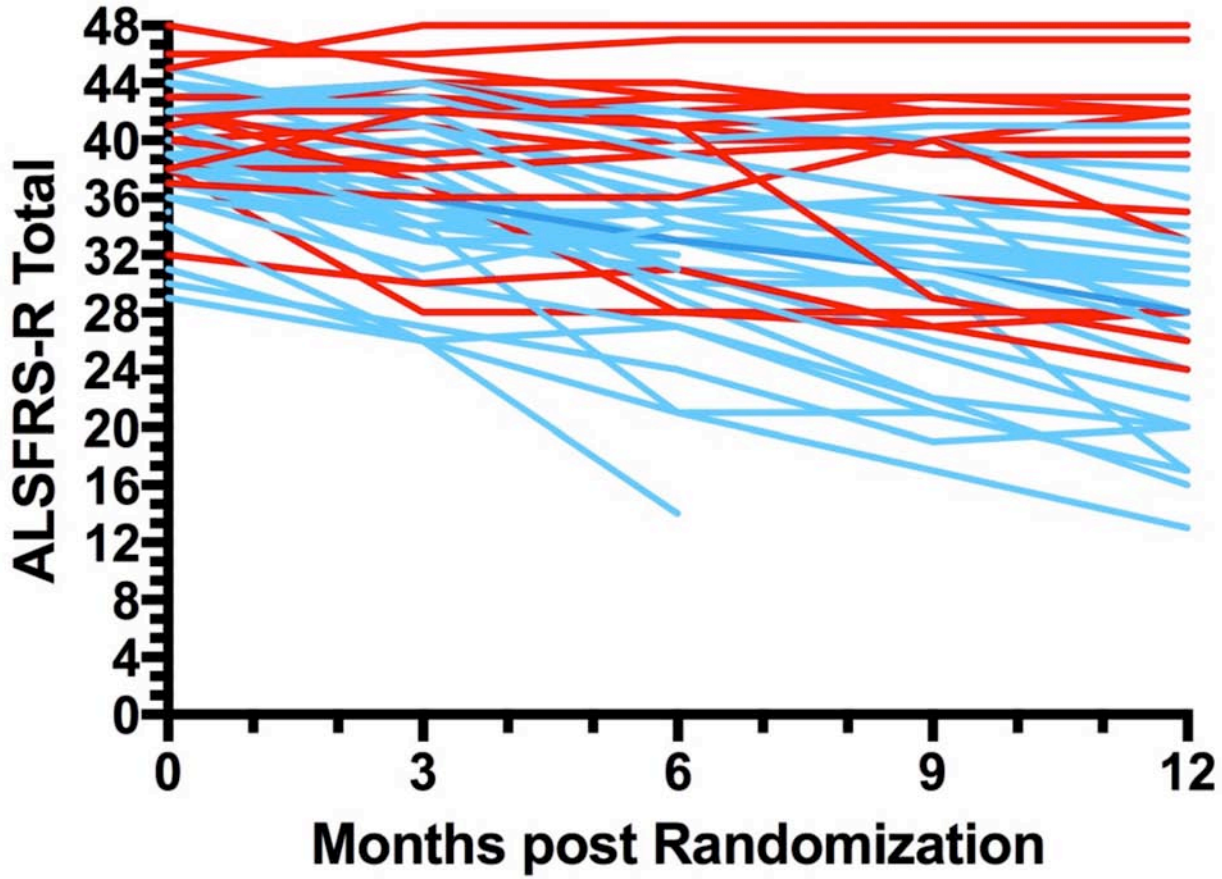
ALSFRS-R Responders



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Adaptive Protocol

Novel Composite Endpoint

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Novel Composite Endpoint

Composite Endpoint

[a] < 12 unit Drop in ALSFRS-R total score
at end of OLE phase

[b] < 1 MMT unit drop in Neck and/or Leg muscles
at end of OLE phase

Ibudilast = 11/34

Placebo = 2/17

Chi-Square = 2.5294

P = 0.1117

Ibudilast therapy associated with proportionately more non-progressors compared with placebo therapy

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Adaptive Protocol

Relation of Novel Composite Endpoint to Survival

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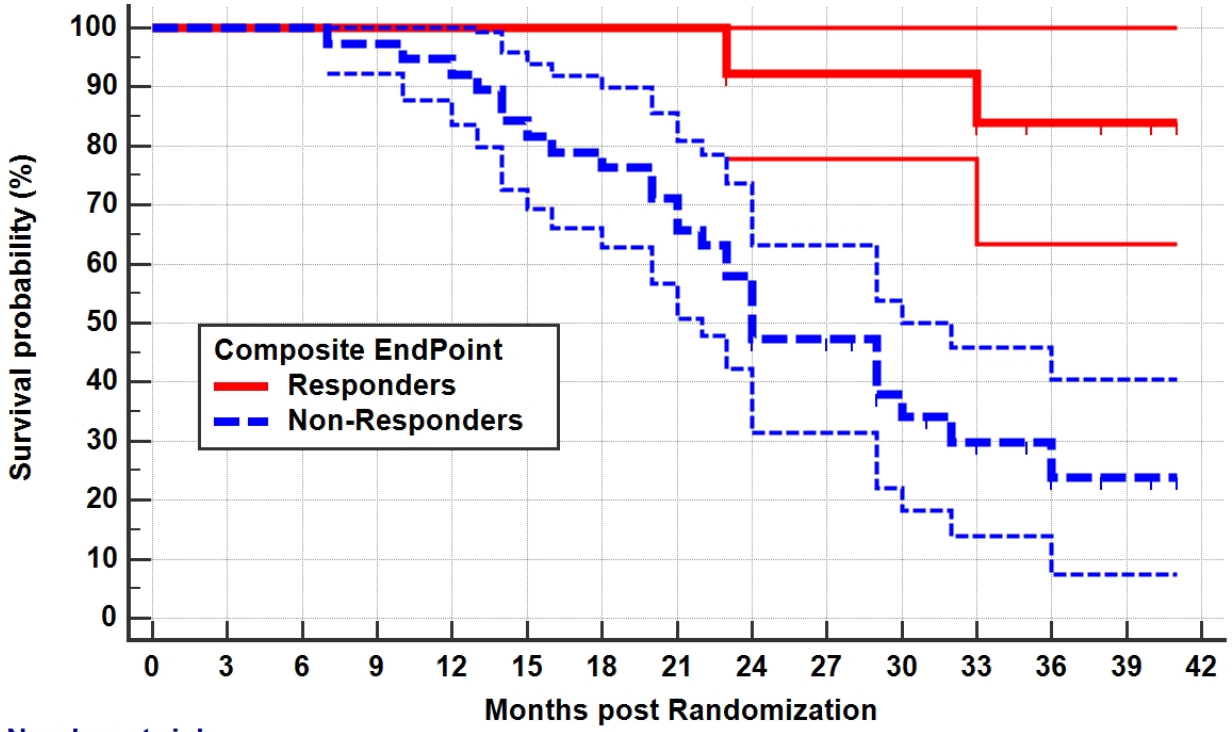
Composite Endpoint and Survival



Number at risk

Group: Responders	13	13	13	13	13	13	13	13	11	11	11	8	7	4	0
Group: Non-Responders	38	38	38	37	35	31	29	25	17	16	9	6	3	2	0

Subjects who achieved Composite Endpoint during the DB and OLE epochs of the adaptive NCT02238626 clinical trial showed improved survival.

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Composite Endpoint and Survival

Kaplan-Meier survival analysis

Survival time	LABLDeathMon
Endpoint	LADeath1
Factor codes	LAalsfrs_r12NL

Cases summary

	Number of events [a]		Number censored [b]		
Factor	N	%	N	%	Total sample size
0	2	15.38	11	84.62	13
1	26	68.42	12	31.58	38
Overall	28	54.90	23	45.10	51

[a] LADeath1 = 1
[b] LADeath1 = 0

Mean and median survival

Factor	Mean	SE	95% CI for the mean	Median	95% CI for the median
0	38.944	1.428	36.145 to 41.743	-	-
1	26.791	1.724	23.411 to 30.170	24.000	22.000 to 32.000
Overall	29.977	1.533	26.972 to 32.982	30.000	24.000 to 36.000

Endpoint: Observed n	2.0	26.0
Expected n	10.1	17.9
Observed/Expected	0.1989	1.4489

Comparison of survival curves (Logrank test)

Chi-squared	10.8903
DF	1
Significance	P = 0.0010

Hazard ratios[a] with 95% Confidence Interval

Factor	0	1
0	-	7.2852 3.3661 to 15.7671
1	0.1373 0.06342 to 0.2971	-

[a] Column/Row

Subjects who achieved Composite Endpoint during the DB and OLE epochs of the adaptive NCT02238626 clinical trial showed improved survival.

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Adaptive Protocol

Relation of Per Protocol Completion to Survival

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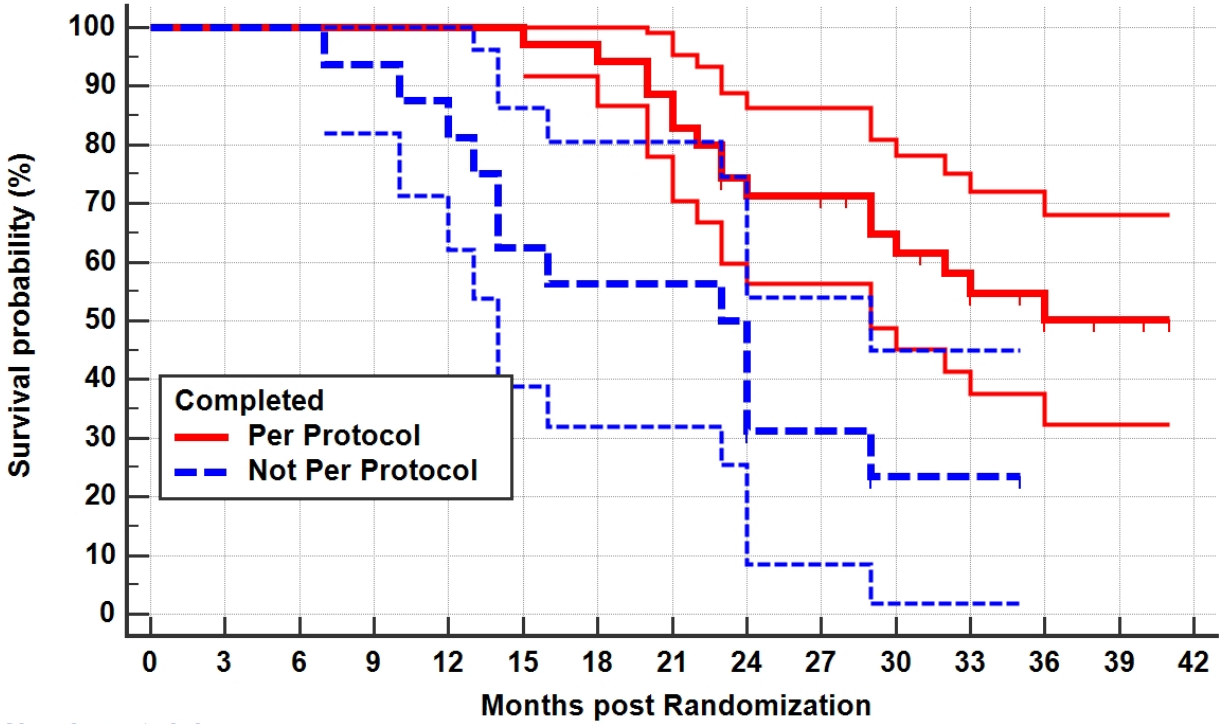
NCT02238626

Per-Protocol and Survival



Number at risk

Group: Per Protocol	35	35	35	35	35	34	33	29	24	23	19	13	10	6	0
Group: Not Per Protocol	16	16	16	15	13	10	9	9	4	4	1	1	0	0	0

Subjects who completed the DB and OLE epochs of the adaptive NCT02238626 clinical trial per protocol showed improved survival.

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Per-Protocol and Survival

Kaplan-Meier survival analysis

Survival time	LABLDeathMon
Endpoint	LADeath1
Factor codes	nPP1

Cases summary

	Number of events [a]		Number censored [b]		
Factor	N	%	N	%	Total sample size
0	16	45.71	19	54.29	35
1	12	75.00	4	25.00	16
Overall	28	54.90	23	45.10	51

[a] LADeath1 = 1
[b] LADeath1 = 0

Mean and median survival

Factor	Mean	SE	95% CI for the mean	Median	95% CI for the median
0	33.236	1.529	30.239 to 36.233	-	-
1	21.781	2.363	17.149 to 26.413	23.000	14.000 to 29.000
Overall	29.977	1.533	26.972 to 32.982	30.000	24.000 to 36.000

Endpoint: Observed n	16.0	12.0
Expected n	22.2	5.8
Observed/Expected	0.7198	2.0790

Comparison of survival curves (Logrank test)

Chi-squared	9.1137
DF	1
Significance	P = 0.0025

Hazard ratios[a] with 95% Confidence Interval

Factor	0	1
0	-	2.8883 1.1561 to 7.2161
1	0.3462 0.1386 to 0.8650	-

[a] Column/Row

Subjects who completed the DB and OLE epochs of the adaptive NCT02238626 clinical trial per protocol showed improved survival.

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Conclusions

Novel composite endpoint defined as

less than 12 units (< 1 unit per month) decrease in ALSFRS-R total score

and/or

not losing 1 MMT unit in neck and leg muscles

in the DB and OLE epochs (12 months) was analyzed.

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Conclusions

11 / 34 ALS subjects randomized [(intention-to-treat (ITT)] to ibudilast compared with 2 / 17 subjects randomized to placebo (P=0.1117) showed no progression.

Subjects (ITT) who showed no progression on 6 or 12 months ibudilast showed improved survival (P=0.0010) in the 30 months post ibudilast treatment.

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Conclusions

Subjects who completed 6 or 12 months ibuidlast treatment [per-protocol (PP)] showed improved survival (P=0.0025) in the 30 months post ibudilast treatment.

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Conclusions

Multiple Myeloma

treatment epoch biomarker response survival

Stem Cell Therapy

treatment epoch biomarker response survival

Gene Therapy

treatment epoch biomarker response survival

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Carolinas Neuromuscular / ALS-MDA Care Center

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NCT02238626 Supported by

MEDICINOVA

Logistical and Statistical Support
Clinical Study Drug and Placebo
Clinical Trials Grant

Carolinas HealthCare System

CMC - Neurology
Carolinas Neuromuscular / ALS-MDA Center
CMC - Neurology Research Division
CHS - Office of Clinical and Translational Research
CHS - Dickson Advanced Analytics DA²

STUDYTRAX

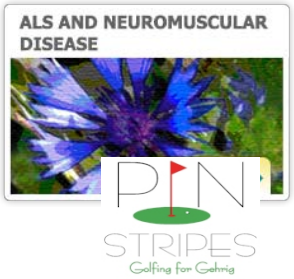
Answers to ALS
STUDYTRAX
1. Collaborate 2. Specialize 3. Inform

Clinical Trials Database Development / Support

Carolinas HealthCare Foundation

MDA Muscular Dystrophy Association
ALS DIVISION

Standard of Care
Patient Care Services Grant
MDA ALS Outcomes Registry



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