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Safety of Plasma Infusions in Parkinson's disease

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Abstract

Background: Young plasma infusions have emerged as a potential treatment for neurodegenerative disease and convalescent plasma therapy has been used safely in the management of viral pandemics. However, the effect of plasma therapy in Parkinson's disease (PD) is unknown.

Objectives: To determine the safety, tolerability and feasibility of plasma infusions in people with PD.

Methods: Fifteen people with clinically-established PD, at least one cognitive complaint, and on stable therapy received one unit of young fresh frozen plasma (yFFP) twice a week for four weeks. Assessments and adverse effects (AEs) were performed/reported on and off therapy at baseline, immediately after, and four weeks after the infusions ended. AEs were also assessed during infusions. The primary outcomes were safety, tolerability, and feasibility. Exploratory outcomes included: UPDRS III off medication, neuropsychological battery, PDQ-39, inflammatory markers (TNF-α, IL-6), uric acid and quantitative kinematics.

Results: Adherence rate was 100% with no serious AEs. There was evidence of improvement in phonemic fluency ($p = 0.002$) and in the PDQ-39 Stigma sub-score ($p = 0.013$) that were maintained at the delayed evaluation. Elevated baseline TNF-α levels decreased four weeks after the infusions ended.

Conclusions: yFFP was safe, feasible, and well-tolerated in people with PD, without serious AEs and with preliminary evidence for improvements in phonemic fluency and stigma. The

results of this study warrant further therapeutic investigations in PD and provide safety and feasibility data for plasma therapy in people with PD who may be at higher risk for severe complications of COVID-19.

Introduction

Interest in the potential therapeutic role of young plasma infusions for neurodegenerative diseases arose following demonstrations that infusion of young rodent plasma into older rodents counteracted aging at the molecular, structural, and functional levels in the hippocampus with beneficial effects on cognitive impairment[1,2]. In Alzheimer's disease (AD) animal models, young plasma infusions reduced neuroinflammatory markers[3] and in humans, platelet rich plasma infusions have an anti-inflammatory effect via reduction of TNF-α and other neuroinflammatory compounds[4]. These and other pre-clinical findings were quickly translated into the clinical setting after it was demonstrated that young fresh frozen plasma (yFFP) infusions in patients with Alzheimer's disease (AD) were well-tolerated without any serious adverse effects[5].

Parkinson's disease (PD) is characterized by motor and non-motor symptoms, including cognitive and mood dysfunction[6]. AD and PD have overlapping neuropathological processes[7], suggesting that treatments that slow neurodegenerative processes in one may also be therapeutic in the other; however, there have been no investigations of the safety, feasibility or efficacy of yFFP in either animal models of Parkinsonism or in human subjects with Parkinson's disease.

Passive immunity after the administration of pathogen-specific antibodies was first developed in 1880 to treat infectious diseases when no vaccines and/or treatment were available[8].

Initially, sources of such antibodies were from the serum of stimulated animals, after which human blood from convalescent patients was also identified as a source[9]. Human convalescent plasma was first identified as a potential therapy during the Spanish flu pandemic of 1918-1920, and subsequent meta-analysis revealed reduced mortality risk in the treated patients[10,11]. To date, convalescent plasma therapy has been used safely in the treatment of the SARS, MERS and H1N1 viral epidemics, and early reports suggest that this may be a promising intervention in the COVID-19 pandemic[12–17].

Young and convalescent plasma differ only in the specific antibodies targeted in convalescent plasma; both contain a mixture of inorganic salts, organic compounds, water, and more than 1000 proteins, such as albumin, immunoglobulins, complement, coagulation and antithrombotic factors. The presence of other proteins such as anti-inflammatory cytokines have been shown to provide immunomodulatory effects, in which elevated levels of pro-inflammatory cytokines, including TNF-alpha and IL-6, are reduced[15,21].

Overall, both young and convalescent plasma infusions have been well tolerated in healthy adults, although adverse events, such as skin and allergic reactions, have been routinely documented[5,22]. Antibody-dependent enhancement (ADE) resulting in an increase in the intensity of infection may occur with the use of convalescent plasma, in which antibodies that are supposed to protect the host actually facilitate viral entry and replication in the target cell[23]. The possibility of ADE is a concern in the development of immunotherapies and vaccines and potentially as an unforeseen adverse event from young plasma infusions. People with

Parkinson's disease (PD) may be at a higher risk of severe complications of COVID-19 and for adverse effects of plasma therapies due to older age, susceptibility to pneumonia, concomitant physical morbidity and evidence of underlying neuroinflammation that has led to autoimmune mechanisms of disease pathogenesis[18–20].

The goal of the present study was to establish the safety, feasibility, and tolerability of yFFP intravenously administered to patients with moderate-stage PD in an open-label, Phase I clinical trial. Exploratory outcomes aimed to establish the effect of yFFP infusions on the domains of motor function, cognition, mood, quality of life and inflammatory blood markers. The results of this study are important not only in the potential development of plasma therapy for PD, but also for PD people who might be candidates for convalescent plasma therapy in the COVID-19 pandemic.

Methods

Human Subjects and Enrollment Criteria

Target enrollment for the study was fifteen patients with idiopathic PD. Inclusion criteria included: a diagnosis of clinically established PD for at least two years with a ≥30% improvement in the MDS-Unified Parkinson's Disease Rating Scale (motor, UPDRS III) score on compared to off therapy, age of 50-80 years, on stable therapy (dopaminergic medication and/or deep brain stimulation (DBS) parameters) for at least 4 weeks prior to screening and throughout the duration of the study, at least one cognitive complaint with a Montreal Cognitive

Assessment[24] (MoCA) score between 23-28, and a stated willingness to comply with the trial protocol.

Exclusion criteria included: a medical history of gout, congestive heart failure, renal failure, uncontrolled atrial fibrillation, stroke, anaphylaxis, blood coagulation disorder, or immunoglobulin A (IgA) deficiency; participation in any other interventional clinical trial; the inability to travel to Stanford for baseline, outcome, or infusion visits; a non-ambulatory state (Hoehn and Yahr Stage V[25]) in the off or on therapy state; clinically determined dementia; clinical suspicion or diagnosis of atypical forms of Parkinsonism or Essential Tremor; pregnancy or an unwillingness to use an adequate birth control method for the duration of and 6 months beyond study participation; positive test results for Hepatitis B, Hepatitis C or HIV at screening; treatment with any human blood product (including intravenous immunoglobulin) during the 6 months prior to screening or during the trial; concurrent daily treatment with benzodiazepines, typical or atypical antipsychotics, long-acting opioids, or other medications that, in the investigator's opinion would interfere with cognition; or any other condition or situation that the investigator believed may interfere with the safety of the patient or the intent and conduct of the study.

The study was approved by the Stanford University Institutional Review Board (IRB) and registered as NCT02968433 at ClinicalTrials.gov. All participants consented by completing an IRB-approved written informed consent form prior to completing any study-related testing.

Trial Design

The trial required patients to attend 14 research visits: two baseline screening neurological visits (on and off therapy), eight infusion visits (twice a week for four weeks), two neurological visits immediately following the last infusion (on and off therapy), and two neurological visits one month after the last infusion (on and off therapy). The neurological visits at baseline, immediately following the last infusion, and one month after the last infusion included a neuropsychological evaluation while the patient was on therapy.

The initial infusion visit was scheduled within two weeks of the baseline neuropsychological and lab testing. One unit (approximately 250 mL) of young plasma was administered per visit, twice a week for four consecutive weeks (eight infusion visits). The patients' last infusion was always completed in the morning, so that the on therapy, immediate outcome testing was completed on the same day; the off therapy immediate outcome visit was performed the following morning. The same comprehensive testing, both on and off therapy, was repeated over two days, four weeks after the last plasma infusion. Details of the infusion protocol can be found in Supplementary Information.

Baseline and Outcome Testing

At baseline, all patients were tested in their best on therapy state and again the following day in the practically-defined off state. Long-acting dopaminergic medications were withdrawn over 24 hours and short-acting medications were withdrawn over 12 hours prior to off therapy visits. For those on DBS, stimulation was turned off at least 15 minutes before any experiments took place[26]. Baseline, immediate post- and delayed post-infusion assessments included the

MDS-UPDRS III on and off therapy, the UPDRS IV (Complications of Therapy scale), on therapy cognitive testing[27], and a repetitive Wrist Flexion Extension (rWFE) task, detailed in Supplementary Information. The off therapy UPDRS III was additionally scored, using shuffled video records, by another certified rater who was blinded to the study visit.

Neuropsychological visits occurred the same day as the neurological on-therapy visits, immediately following the last infusion and again, one month after the last infusion. The battery was administered by a neuropsychologist and is detailed in Supplementary Information. Quality of life (QOL) changes were tracked using the self-report Parkinson's Disease Questionnaire-39 (PDQ-39)[7]. Blood levels of tumor necrosis factor-alpha (TNF-α), interleukin-6 (IL-6), and uric acid were also drawn at baseline and outcome visits.

Data collection and analysis

All data was entered in REDCap[28], a secure, HIPAA-compliant database that was accessible by research staff only. Adverse events (AEs) were recorded through REDCap and categorized using the Common Terminology Criteria for Adverse Events (Version 4.0). Adherence rate was calculated for each patient and defined as the quotient of the total number of study visits attended divided by the total number of scheduled study visits. AEs were reviewed by one or both movement disorders neurologists (HBS, ML) and the transfusion medicine specialist (NS), and subsequently categorized based on the likelihood that a discrete event was related to the study intervention (probably, possibly, or not related).

Raw scores and normative scores were calculated for all cognitive, mood and QOL measures according to standardized procedures across all three time points. Exploratory outcomes were conducted to determine change from baseline for the measures reported above.

Statistics

All analyses were performed using R 3.5.0[29]. Linear mixed effects models with a random intercept for patient were used to model the effect of visit on outcomes of interest. These models are robust to missing observations under mild missingness assumptions, such as missing completely at random (MCAR), and allow for the inclusion of participants who are missing data from one or two observation periods. Missingness was not especially prevalent in this data, and where present, it was due to an arguably MCAR process (lost or corrupted video data). Visit was modeled categorically and its statistical significance was assessed via the Satterthwaite F-test. This test produces a single p value for visit for each model. Additionally, each model was used to estimate mean outcomes at each visit as well as differences between outcomes from visit to visit. Given the exploratory nature of these analyses, no adjustments for multiple testing were made.

Results

From fifty-four people with PD who were phone-screened, twenty-one provided written consent to participate in the study. After consent but prior to establishing study visits, two patients were exited: one was unwilling to be tested off therapy and one was unwilling to commit to the study visit schedule. At baseline, three patients failed to meet screening criteria and were exited from the study before treatment began: two patients had MoCA scores above the inclusion

range and one patient did not satisfy the MDS clinical diagnostic criteria for Parkinson's disease[30].

Table 1 details the demographic data of the fifteen patients (5 women) who completed the study. The PD cohort was representative of moderate-stage PD with a mean ± standard deviation age of 63 ± 8.30 years and disease duration of 7.93 ± 3.51 years, and with 16.87 ± 2.42 years of education. At baseline, all patients exhibited a good response to dopaminergic medication (mean UPDRS III off and on medication scores were 34.67 ±15.05 and 18.13 ± 11.99, respectively), did not have dementia, and had a mean baseline MoCA score of 26.60 ± 1.59.

[Table 1]

Primary Outcomes

yFFP infusions were safe and well tolerated. No serious adverse events were reported throughout the course of the study; however, several mild AEs occurred. AEs included: transient skin reactions; involuntary movements; and musculoskeletal, central nervous system, or systemic symptoms, Table 2. Infusions did not cause volume related AEs or abnormal lab values. Comprehensive blood tests, including complete blood count, chemistries, and liver and kidney function tests, were not adversely affected by the plasma infusions.

[Table 2]

Among the sixteen patients for whom study visits were set up, 53 minor adverse events were reported, of which fourteen (26.42%) were categorized as probably related (Table 2). Three (5.66%) adverse events were possibly related and thirty-six (67.92%) were categorized as not

related. Mean adherence rate, was 95.83% for the sixteen patients and was 100% after accounting for the one patient's decision to withdraw early from the study after experiencing a macular rash more than twenty-four hours after the second infusion. The rash was not observed by study personnel as it had resolved by the time the patient was evaluated. The patient also admitted to eating unusual food that day and did not experience any skin reaction during either of the two infusions.

Exploratory Outcomes

There was immediate and maintained improvement in phonemic fluency and in one PDQ-39 sub-score (Stigma: self-perceived negative attributes), Table 3. There was no significant change in any other cognitive or quality of life scores. There was immediate and maintained improvement in the off therapy unblinded total UPDRS III scores, and in both the more and lesser affected unblinded lateralized scores and, Table 3; however, there was no significant change detected in the off therapy blinded rater video assessment of the UPDRS III scores. The trend was toward improvement with a 2.04 decrease in median blinded UPDRS III (excluding rigidity) scores at the four week post infusion visit; the clinically important difference for the total UPDRS III is 2.3-2.7[31]. Patients did not experience any plasma-related complications of therapy, as measured by the UPDRS IV, and did not experience additional freezing of gait disturbances related to the study intervention, as measured by the FOG-Q, Table 3.

[Table 3]

Baseline elevated inflammatory markers were lower four weeks after plasma infusions

Exploratory observation revealed that eight out of fifteen (53.33%) patients had elevated plasma TNF-α levels at baseline (TNF-α > 22), which decreased in all eight patients at the delayed (four weeks post infusion) evaluation, Table 4. Table 4 demonstrates that six out of the eight patients who had elevated baseline TNF-α levels reported one or more skin reactions during infusions. Only one patient with a normal baselined TNF-α, reported a skin reaction.

[Table 4]

Baseline IL-6 levels were normal in thirteen out of fifteen patients and remained normal after the infusions and baseline uric acid levels were normal in all but one of the patients, Supplementary information, Table S1.

Quantitative kinematics

Twelve patients completed the rWFE task at baseline and at both outcome visits. In the patients who completed the task at all three time points, there was no significant change in the mean angular velocity (Vrms), the variability of mean angular velocity, (CV Vrms), or the regularity of the interstrike interval (CV ISI) in the more or lesser affected hands, Table 5.

[Table 5]

Discussion

This is the first study demonstrating that four weeks of twice weekly infusions of one unit of young fresh frozen plasma (yFFP) in people with clinically-established Parkinson's disease was safe, feasible, and well tolerated with no serious adverse events. One patient voluntarily withdrew after experiencing a transient macular rash over twenty-four hours after receiving the

second infusion, which was categorized as unrelated, and the adherence rate was 100% in the remaining fifteen patients. The most common adverse effects were mild skin reactions during infusions, which are common during clinical plasma infusions but still may be a source of discomfort for people with PD[32].

Preliminary evidence of the therapeutic effect of young plasma infusions for PD

Analysis of cognitive and QOL exploratory outcomes revealed significant improvements in phonemic fluency and in the Stigma sub-score of the PDQ-39. Improvements in both phonemic fluency and in the Stigma sub-score were evident immediately after the infusions and did not deteriorate after a four-week washout of the infusions. The degree of cognitive impairment in this study was mild overall. Though not at ceiling, the group mean score for each cognitive measure fell within the normal range. There were three patients with MoCA scores lower than 26, which is the suggested cut-off for cognitive impairment in PD, and three patients had a baseline MoCA score of 26. Four patients met criteria for MCI Level 1[33] when taking into consideration the complete test battery. Specifically, on the phonemic verbal fluency task, only four patients had scores below the normal range, (i.e., 1 standard deviation below the mean) based on demographic normative data.

Verbal fluency tests both verbal ability and executive control and is one of the most common early-stage cognitive deficits in PD; impaired phonemic fluency has been correlated with smaller caudate volumes in early stage PD[34–37,38]. There was no control group in this Phase I study but the baseline phonemic fluency scores in this cohort were similar to those from a

different cohort of thirty-six PD patients (of similar age and education), whose phonemic fluency scores were significantly lower than fifty-two age matched controls, Table 3[35]. Although it has been determined that the practice effect for repeated cognitive testing is small among PD patients[39], this same study determined that a reliable change index in phonemic fluency would be of the order of an increase of 11.09 or a decrease of 12.69 in the phonemic fluency correct score. In the current study, the median improvement was below this and only three out of fifteen patients showed an improvement that would be considered reliable. As such, although the improvement in this study was significant, it should be regarded as preliminary.

In designing this first of its kind study in Parkinson's disease, we targeted people with moderate-stage PD and mild cognitive deficits (MoCA 23-28), rather than focusing on those with dementia. Dementia is usually encountered in later stages of idiopathic PD[40], and as it has been proposed from animal literature that any effect of young plasma therapy may be restorative in nature[1,2,41], we hypothesized that yFFP infusions would be more likely to demonstrate a difference in early to moderate stages of neurodegeneration, when the cell loss and pathological burden was not extreme. Phonemic fluency may be such a task that is impaired in earlier stages of PD and possibly sensitive to such interventions.

The experience of stigma by people with PD reflects their perceived negative image in and reception by society, that may lead to shame, embarrassment and withdrawal from public spaces[42]. Experienced stigma has been shown to be a key determinant of overall quality of life in PD and has been shown to have a higher correlation with QOL than with depression or motor

difficulties of daily living[43]. The maintained improvement of stigma after yFFP infusions may make a meaningful difference to PD patients' quality of life. This result should be interpreted as preliminary, due to the potential of a placebo effect of a Phase I study, but suggests that inclusion of stigma and other quality of life scores will be important in larger placebo-controlled studies of the efficacy of yFFP for PD.

Analysis of the blinded UPDRS III scores revealed no significant improvement after yFFP infusions although there was a downward trend of the median UPDRS III scores, Table 3; the difference in the mean UPDRS III from baseline to the four weeks post infusions was 2.04, slightly below the clinically important difference (CID) for the UPDRS III of 2.3 - 2.7[31]; however, the blinded scores did not include rigidity, so the CID may be lower. These analyses omitted one patient, whose baseline video was missing, and only gave one statistical outcome despite two outcome time points. The unblinded UPDRS III scores demonstrated significant improvement both immediately and four weeks post infusions; however, during analysis, it was determined that the largest discrepancy between the blinded rater's scores and those of the unblinded dataset were in the baseline scores. As such, we believe that the unblinded UPDRS III scores are interesting, but less reliable.

Reduction in peripheral inflammatory markers after young plasma infusions

Exploratory observations demonstrated that eight out of fifteen patients had an elevated peripheral tumor necrosis factor (TNF)-α level at baseline, which was lower four weeks after the end of the yFFP infusions in all of the eight patients; there was no elevation of the normal

baseline TNF-α levels in the other seven patients post infusions. Six out of the eight patients with elevated baseline TNF-α levels experienced one or more skin reactions during infusions. It is unclear whether the elevated TNF-α status directly contributed to skin reactivity, but it was interesting that only one out of seven patients with normal baseline TNF-α had a skin reaction, which did not occur until the 7th infusion. Skin reactions occurred in a larger percentage of the present PD cohort than was seen in the AD cohort[5].

TNF-α is a pro-inflammatory cytokine that has been shown to be elevated in post-mortem brains of people with PD and in animal models of Parkinsonism[44–49]. McCoy et al. (2006) demonstrated that soluble TNF signaling was responsible for nigral dopaminergic neuron loss in the 6-OHDA rodent Parkinsonian model, either by neuroinflammatory mechanisms or oxidative toxins[50]. Inhibition of soluble TNF reduced neuroinflammation and dopaminergic neuron loss, suggesting it may be a molecular source of disease progression and a potential point of intervention for disease-modifying therapies. Whether reducing peripheral TNF-α translated to a reduction in central TNF concentrations remains to be demonstrated, but this preliminary data suggests a potential anti-inflammatory role for yFFP therapy in Parkinson's disease and would support the use of plasma therapy in PD people with severe COVID-19 infection and evidence of an elevated immune response. This study was not powered to compare the improvement in inflammatory markers with motor or cognitive improvement, making this an important area for further investigation.

Limitations

As there are no pre-clinical investigations of young plasma infusions in Parkinsonian animal models and this initial trial was a Phase I feasibility study, these exploratory outcomes should be taken as preliminary, given the possible placebo effect. The cohort was small and all results including safety are non-generalizable; the study's statistical model did not adjust for multiple testing and no statistical analysis was performed on the exploratory analysis of the blood markers as the study was not powered for this and values were reported as ranges rather than absolute values.

Conclusions

Four weeks of twice weekly yFFP infusions were safe, feasible, and well-tolerated in moderate stage PD with no serious adverse events and a 100% adherence rate in fifteen people. Exploratory outcome measures indicated significant immediate and maintained improvements in phonemic fluency and in the Stigma subscore of the PDQ-39. A majority of patients had elevated markers of peripheral inflammation at baseline which were decreased four weeks post infusion, indicated via a reduction in peripheral TNF-α. Although the unblinded UPDRS III scores improved, they did not remain significant after the blinded UPDRS III scores were calculated. The results of this study demonstrate that yFFP was safe in a small cohort with PD and with potential therapeutic effects, warranting further investigation into the potential anti-neuroinflammatory mechanism of plasma in larger, multicenter, double-blinded clinical trials. These results also support the safety of cautious use of plasma therapy in PD people with severe COVID-19 infection.

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3. Manuscript: A. Drafting, B. Critical Revision
4. Statistical Analysis
5. Administrative support
6. Database auditing

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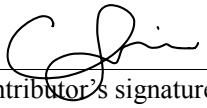

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Exploratory Outcomes

Test	Baseline	Immediate	Delayed	P
NEUROPSYCHOLOGICAL/COGNITIVE TESTS				
Wechsler Abbreviated Scale of Intelligence-II (WASI-II)				
Block Construction	34.73 (27.45, 42.02)	35.60 (28.32, 42.88)	37.47 (30.18, 44.75)	1
Matrix Reasoning	17.47 (14.87, 20.06)	17.27 (14.67, 19.86)	20.13 (17.54, 22.73)	1
Symbol Digit Modalities Test				
Written	44.80 (39.14, 50.46)	47.07 (41.40, 52.73)	49.40 (43.74, 55.06)	0.090
Oral	53.67 (46.89, 60.44)	57.40 (50.62, 64.18)	57.73 (50.96, 64.51)	0.323
Trail Making Test				
Part A	32.53 (27.63, 37.44)	29.27 (24.36, 34.17)	29.07 (24.16, 33.97)	1
Part B	83.20 (62.64, 103.76)	72.87 (52.31, 93.42)	73.53 (52.98, 94.09)	1
Verbal Fluency				
Phonemic (COWAT; Letters-FAS)	41.13 (34.75, 47.52)	44.73 (38.35, 51.12)	48.07 (41.68, 54.45)	**0.002**
Semantic (Animal Naming)	21.40 (19.17, 23.63)	22.40 (20.17, 24.63)	23.07 (20.84, 25.29)	1
CogState^{TM} (GML)	71.47 (53.15, 89.79)	54.87 (36.55, 73.19)	60.53 (42.21, 78.85)	1
MOOD				
Beck Anxiety Inventory	10.66 (6.06, 15.25)	7.60 (3.05, 12.15)	8.47 (3.92, 13.02)	1
Beck Depression Inventory	9.92 (5.69, 14.15)	8.13 (3.93, 12.34)	8.07 (3.86, 12.27)	1
QUALITY OF LIFE				
PDQ-39 (Total Score)	71.81 (59.51, 84.10)	66.73 (54.49, 78.98)	64.40 (52.16, 76.64)	0.253

Mobility	17.33 (13.38, 21.28)	16.47 (12.53, 20.41)	15.80 (11.86, 19.74)	1
Activities of Daily Living	12.05 (10.29, 13.82)	11.60 (9.85, 13.35)	10.53 (8.79, 12.28)	0.286
Emotional well-being	10.60 (7.75, 13.45)	10.13 (7.30, 12.97)	10.00 (7.16, 12.84)	1
Stigma	7.42 (6.22, 8.63)	6.20 (5.01, 7.39)	5.53 (4.34, 6.72)	**0.013**
Social support	5.57 (3.99, 7.16)	5.00 (3.43, 6.57)	5.33 (3.76, 6.90)	1
Cognition	6.90 (5.53, 8.28)	6.87 (5.50, 8.23)	6.80 (5.43, 8.17)	1
Communication	5.33 (4.31, 6.36)	5.20 (4.19, 6.21)	4.60 (3.59, 5.61)	1
Bodily discomfort	6.53 (5.25, 7.82)	5.27 (4.00, 6.53)	5.80 (4.53, 7.07)	0.734
MOTOR				
Unblinded UPDRS III Score	34.67 (27.95, 41.38)	26.13 (19.42, 32.85)	25.20 (18.48, 31.92)	< 0.001
More affected	15.27 (12.29, 18.24)	11.47 (8.49, 14.44)	11.73 (8.76, 14.71)	< 0.001
Less affected	9.33 (6.95, 11.72)	7.47 (5.08, 9.85)	6.60 (4.22, 8.98)	0.007
Blinded UPDRS III Score (excluding rigidity)	21.43 (15.84, 27.01)	19.77 (14.13, 25.42)	19.39 (13.74, 25.03)	0.483
More affected	9.21 (6.72, 11.71)	7.59 (5.06, 10.12)	7.66 (5.14, 10.19)	0.141
Less affected	4.64 (3.07, 6.21)	4.55 (2.95, 6.15)	4.84 (3.24, 6.44)	0.907
Freezing of Gait Questionnaire	4.57 (2.58, 6.56)	4.57 (2.58, 6.56)	4.50 (2.51, 6.49)	0.995
UPDRS IV	4.77 (3.11, 6.43)	3.81 (2.09, 5.54)	4.67 (2.98, 6.35)	0.188

Table 3. Exploratory outcomes (means and 95% confidence intervals) for all neuropsychological, mood, quality of life and motor tests/questionnaires. Significant p values are indicated in bold.

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Contributor address: 7630 Wood Hollow Dr Apt 247 Austin, TX 78731

Manuscript number: MDS-20-0555

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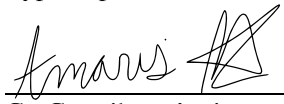

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Patient Demographics

Patient	Age	Disease duration (years)	MoCA score	Baseline UPDRS III off therapy	Baseline UPDRS III on therapy	Hoehn & Yahr (Off therapy)
1	71	9	28	28	13	2
2	71	7	26	27	15	2
3	51	7	28	38	22	2
4	64	8	27	51	15	3
5	56	9	24	39	16	2
6	55	13	25	54	38	2
7	70	5	27	26	15	3
8	58	7	28	28	12	2
9	51	6	28	51	17	2
10	74	4	27	56	47	2
11	69	14	28	46	31	2
12	55	9	26	11	7	2
13	66	14	23	37	14	3
14	74	4	28	16	8	2
15	60	3	26	12	2	2
M (SD)	**63 (8.30)**	**7.93 (3.51)**	**26.60 (1.59)**	**34.67 (15.05)**	**18.13 (11.99)**	**2.20 (0.41)**

Table 1. Demographic data for each patient; M(SD) = mean (standard deviation).

Adverse Events

Probably Related AE	**No. (%)**
Bruising	1 (1.89)
Skin and subcutaneous tissue disorder	13 (24.53)
Possibly Related AE (by category)	**No. (%)**
Cough	2 (3.77)
Hypotension	1 (1.89)
Unrelated AE	**No. (%)**
Nervous system disturbance	4 (7.55)
Bloating	1 (1.89)
Urinary frequency disturbance	2 (3.77)
Stomach pain	1 (1.89)
Back pain	1 (1.89)
Involuntary movements	8 (15.09)
Musculoskeletal and connective tissue disorder	4 (7.55)
Chest tightness	1 (1.89)
Sore throat	1 (1.89)
Fall	1 (1.89)
Flu-like symptoms	2 (3.77)
Tremor	1 (1.89)
Generalized muscle weakness	1 (1.89)
Sleep decrease	2 (3.77)
Headache	2 (3.77)

Skin and subcutaneous tissue disorder	2 (3.77)
Gastrointestinal	1 (1.89)
Pain in extremity	1 (1.89)

Table 2. Categorization of AEs based on likelihood of relatedness to intervention. No. (%) = number of AE's in a specific category and percentage of the total AE's in that category. Table includes data for patients who received at least 1 infusion.

Skin Reactions and TNF-α levels Pre- and 4weeks Post Infusions

Patient	Skin AE	TNF-α (pg/mL)	
		Baseline	Delayed
1	None	**59**	21
2	None	< 5	3.4
3	Itching and hives, three different limbs	**173**	2.5
4	Itchiness, two hives	**107**	**71**
5	Urticaria, welts, bumps behind ear, redness of face	**24**	2.4
6	None	16	2.4
7	None	**50**	4.6
8	Itchiness behind left ear, chest and back; hives; swelling of inner left eye duct and eyelid	**946**	2.7
9	Welts on temple and left arm, rash acneiform, small red blotches on back	**96**	**30**
10	Swollen right inner arm	**195**	20
11	None	< 5	< 5
12	None	< 5	< 5
13	None	< 5	< 5
14	Welt on left side of chest	5	< 5
15	None	< 5	< 5

Table 4. All patients' baseline TNF-α levels, types of skin reaction experienced, if any, and four weeks post-infusion TNF-α levels. Abnormal values are indicated in bold text. Normal range is ≤ 22 pg/mL.

rWFE Quantitative Bradykinesia Outcomes (off therapy)

Metric	Baseline	Immediate	Delayed	P
MA Vrms (deg/sec)	305.13 (196.72, 413.54)	339.66 (231.24, 448.07)	312.39 (203.98, 420.81)	0.60
MA CV Vrms	0.29 (0.20, 0.38)	0.19 (0.10, 0.29)	0.26 (0.17, 0.35)	0.87
MA CV ISI	0.16 (0.07, 0.26)	0.11 (0.01, 0.20)	0.17 (0.08, 0.27)	0.94
LA Vrms	414.47 (295.08, 533.86)	411.26 (291.87, 530.65)	403.00 (283.61, 522.39)	1
LA CV Vrms	0.16 (0.09, 0.22)	0.17 (0.12, 0.24)	0.18 (0.11, 0.24)	1
LA CV ISI	0.09 (0.05, 0.14)	0.09 (0.04, 0.13)	0.10 (0.05, 0.15)	1

Table 5. rWFE quantitative bradykinesia outcomes (means and 95% confidence intervals) for mean angular velocity (Vrms), the variability of mean angular velocity, (CV Vrms), and the regularity of the interstrike interval (ISI) or rhythmicity (CV ISI) on the more and lesser affected hands (MA and LA, respectively).