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Rationale and design of the theRapeutic effects of peroneal nerve functionAl electrical stimuLation for Lower extremitY in patients with convalescent poststroke hemiplegia (RALLY) study: study protocol for a randomised controlled study

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ABSTRACT

Introduction Increasing evidence supports the utilisation of functional electrical stimulation (FES) to improve gait following stroke; however, few studies have focused exclusively on its use in the convalescent phase. In addition, its efficacy in patients with a non-Western life style has not been evaluated.

Methods and analysis This is a randomised, controlled, open-label multicentre study, comparing rehabilitation with and without FES. The purpose of our study is to test the hypothesis that the FES system improves walking ability in Japanese patients with hemiplegia during the convalescent phase. Two hundred patients aged 20–85 years who had an initial stroke ≤6 months prior to the enrolment, are in a convalescent phase (after the end of acute phase treatment, within 6 months after the onset of stroke) with functional ambulation classification 3 or 4 and have a hemiplegic gait disorder (drop foot) due to stroke have been recruited from 21 institutions in Japan. The patients are randomised in 1:1 fashion to usual gait rehabilitation or rehabilitation using FES (Walkaide). The trial duration is 8 weeks, and the primary outcome measured will be the change in maximum distance from baseline to the end of the trial, as measured with the 6 min walk test (6-MWT). The 6-MWT is performed barefoot, and the two treatment groups are compared using the analysis of covariance.

Ethics and dissemination This study is conducted in accordance with the principles of the Declaration of Helsinki and the Ethical Guidelines for Medical and Health Research Involving Human Subjects and is approved by the ethics committee of all participating institutions. The published results will be disseminated to all the participants by the study physicians.

Trial registration number The University Hospital Medical Information Network-Clinical Studies Registry (UMIN000020604).

Strengths and limitations of this study

- This study is unique in that it evaluates the effectiveness of functional electrical stimulation (FES) use in patients who live bare-footed at home.
- The study has prescreening period to confirm participants' eligibility and tolerability.
- The limitation of the study is the relatively short training time due to the Japanese insurance policy.
- This study will provide important evidence to the use of FES in non-western settings where differences in life style require complex and different muscle movement.

INTRODUCTION

Stroke remains a major cause of disability worldwide, including Japan. A report by the Ministry of Health, Labour, and Welfare suggests that 14% of Japanese patients with stroke (170 000 patients) are part of the working population, burdening the ageing Japanese society.[1] Early rehabilitation is usually recommended after a stroke;[2–5] however, disabilities such as gait disturbance often persist for a long time, and approximately two-thirds of the stroke survivors do not fully regain their function.[6] The Japanese national insurance system has introduced a system to give priority support to patients who have undergone acute treatment (convalescent patients) to improve their long-term functional prognosis.[7] Thus, new approaches for the functional recovery of patients with stroke are awaited.

Stroke patients often suffer drop foot, which is the loss of the ability to dorsiflex the foot on the affected side. Patients with drop

foot cannot hold the foot in a neutral position and it drags during the swing phase of the gait, leading to gait disability.[8] Spastic drop foot exists when, due to a combination of weakness of the ankle dorsiflexors (primary tibialis anterior) and spasticity of the ankle plantar flexors, the ankle has a predisposition for staying pathologically plantar flexed, and it largely affects gait. Traditionally, ankle-foot orthosis (AFO) has been used for drop foot.[9–11] AFO stabilises the foot and ankle and lifts the toes while walking. The short-term effects of an AFO attachment include an improvement in the functional ambulation category (FAC), an increase in walking speed and stride, and a shortening of the Timed Up & Go[12 13]; however, the long-term therapeutic effect is unclear.

Functional electrical stimulation (FES), an alternative drop foot treatment, is designed to restore paralysed motor function by electrically stimulating the neuromuscular system during ambulation. The stimulation to the peroneal nerve provides active dorsiflexion during the swing phase, resulting in increased voluntary muscle activity.[9] Previous studies have shown that FES improves drop foot and the quality of gait in patients with drop foot after stroke, especially patients with FAC 3 or 4;[14–18] however, only a few studies have exclusively focused on individuals in the convalescent period. Furthermore, these studies were mainly conducted in the USA and Europe, where rehabilitation practices, insurance policies and lifestyles differ from those in Japan.[7 19 20] Most FES devices include a foot switch and are intended for use in shoes. Generally, Japanese live barefoot indoors and their lifestyle is different from that of Western countries; for example, many Japanese sit on the floor and use low table while eating or relaxing. Therefore, it is not clear whether FES devices, whose effectiveness have been reported in Western countries, are suitable for use in Japan. Walkaide (Innovative Neurotronics, Reno, Nevada, USA) is suitable for use with bare feet due to the use of the tilt sensor as opposed to the foot switch to activate the FES.[17]

In this study, using this Walkaide device as the FES, we will test the hypothesis that the FES system is effective in improving the walking ability and lower extremity functions in Japanese patients with unstable gait due to hemiplegic stroke.

METHODS AND ANALYSIS

Study design and patient population

The theRapeutic effects of peroneal nerve functionAl electrical stimuLation for Lower extremitY in patients with convalescent poststroke hemiplegia (RALLY) study is a randomised, controlled, open-label multicentre study. The trial enrols patients with hemiplegic gait disorder (drop foot) due to stroke from 21 poststroke rehabilitation centres across Japan. The major inclusion criteria are patients aged 20–85 years, who had an initial stroke ≤6 months prior to the enrolment, with functional ambulation classification (FAC) 3 or 4. The FAC categorise patients according to basic motor skills necessary for functional ambulation. The score ranges from 0 to 5; FAC 3 patients have a walking disability that requires stand-by assistance, whereas patients classified as FAC 4 can walk independently on level ground but requires support on stairs. Based on previous literature, these are the patients who are likely to benefit from training with FES. Those patients who cannot tolerate rehabilitation due to existing conditions such as heart failure or severe osteoarthritis are excluded. For safety reasons, very elderly patients (>85 years), patients with unstable blood pressure, heart rate or blood glucose levels, or patients with severe liver, kidney and cardiovascular dysfunction, are excluded from the study. Patients with other conditions that may render the outcome are also excluded (eg, use of FES or a robot suit within 1 month prior to providing consent or botulinum toxin injections or phenol nerve block injection within 6 month of informed consent, severe sensory dysfunction or higher brain dysfunction). Details of the inclusion and exclusion criteria are listed in box 1. Physician investigators at each participating site are responsible for recruiting patients and obtaining written informed consent. Subsequently, candidate patients were then tested for FES receptivity for a maximum of 7 days (screening period) by the treating physician and physical

Box 1 Inclusion and exclusion criteria of the RALLY study

Inclusion criteria

1. Obtained informed consent.
2. Aged 20–85 years.
3. In convalescence phase of stroke (within 6 months (180 days) after initial stroke onset).
4. Post initial cerebral infarction or haemorrhage stroke (excluding subarachnoid haemorrhage).
5. Hospitalised for stroke rehabilitation.
6. Functional Ambulation Classification category 3 or 4.
7. With stable blood pressure, heart rate and blood glucose level (those who needs additional treatments are excluded).
8. Drop foot while walking.

Exclusion criteria

1. Rehabilitations not recommended due to existing conditions.
2. History of nerve disorder or leg joint diseases affecting gait.
3. Severe liver, kidney and cardiovascular dysfunction.
4. Severe sensory dysfunction or higher brain dysfunction.
5. Contraindication for the use of electrical stimulation therapy.
6. Unable to use electrode pads.
7. Dose change in muscle relaxant drugs.
8. Concomitant treatment affecting the trial outcome at the time of informed consent.
9. Botulinum toxin injections or phenol nerve block injection within 6 months of informed consent.
10. Use of FES or a robot suit for lower limb treatment within 1 month prior to providing consent.
11. Considered not eligible by a physician during the FES trial period.
12. Unable to adjust Walkaide within 7 days.
13. Participation in other clinical trials.

FES, functional electrical stimulation; RALLY, theRapeutic effects of peroneal nerve functionAl electrical stimuLation for Lower extremitY in patients with convalescent poststroke hemiplegia.

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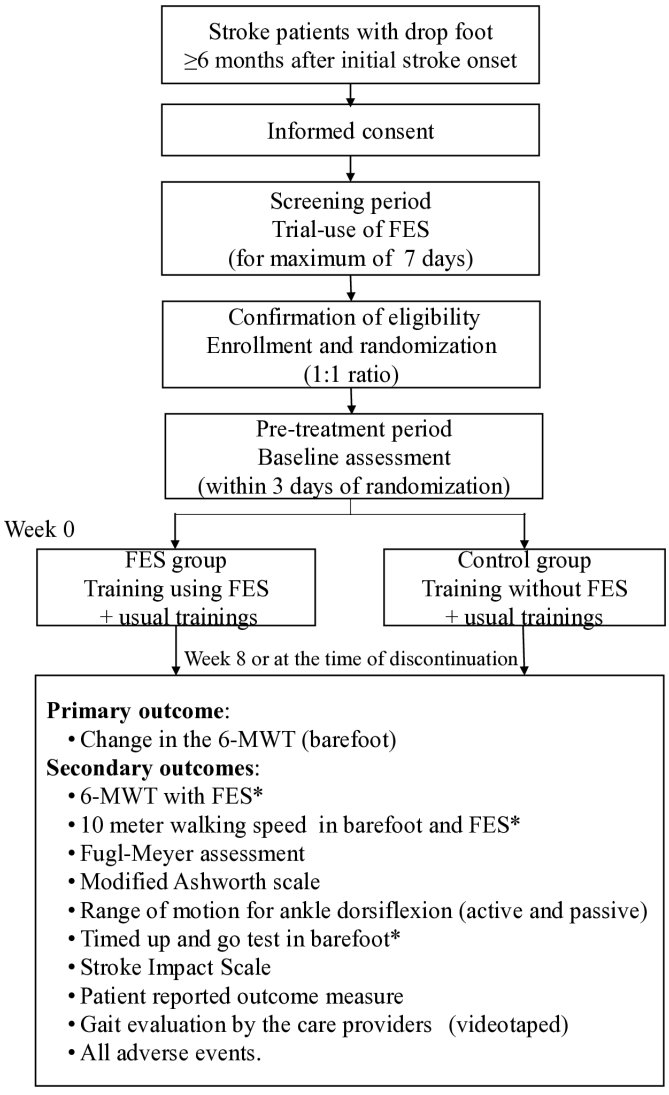

Figure 1 Study schema. Randomised patients undergo 8 weeks of allocated treatment in addition to the usual rehabilitation programme. *Patients who already use AFO at the time of randomisation will perform each test with AFO. AFO; ankle-foot orthosis; FES, functional electrical stimulation; 6-MWT, 6 min walk test.

therapists. Patients were excluded from the study if any of the followings are observed: (1) unresponsive to the FES device, (2) intolerance to continuous stimulation or (3) if gait function improves significantly during the screening period.

After the screening period, eligible patients were randomly sorted to receive either FES training using Walkaide (FES group) or to rehabilitation without FES (control group), in addition to their usual training. Gait abilities and functions will be assessed at each participating site within 3 days after randomisation (pretreatment period) and at the end of the study. The details of the schedule and assessments are summarised in figures 1 and 2.

Data entry is being performed by either the institutional principal investigator (physician) or the subinvestigators (physician or physical therapists) using an electronic data capturing system and is monitored centrally per protocol to promote data quality.

In case of research-related harm, the participating site will be responsible for providing adequate treatment and compensation, as required. Although we do not anticipate any severe side effects, this is a required rule for any trials performed in Japan.

Patient and public involvement

The research question was developed from patients' experiences and needs. The patients were not involved in the design, recruitment or conduction of this study; however, they all consented to the research question and outcome measures. The burden of the intervention was assessed by the patients themselves at the run-in period, and the results of the study will be disseminated to the patients by their treating physicians.

Randomisation

The enrolled patients are randomly allocated to either the FES or control group in a 1:1 fashion with a minimised method using an electronic data capturing system, the eClinical Base (https://www.tri-kobe.org/support/tools/). Randomisation was performed with consideration to the following factors: FAC 3 or 4, age<65 years or not, types of stroke (ischaemic stroke or haemorrhagic stroke) and institution. The institutional principal investigators were responsible for creating an anonymous number control table and for securely concealing the sequence.

Treatment programs

The usual rehabilitation training is defined as a 60 min physiotherapy treatment provided 5 days a week to both the FES and control groups, over 8 weeks, for a total of 40 days. These are based on the Japanese insurance policy, and it is the clinically adopted routine in Japan. The programme consists of basic activity training, including mat exercise, standing up and sitting down and ambulation with assistive devices or support and/or range of motion (ROM) training and/or gait training using an AFO (if the patient is already using it at the time of recruitment).

In addition to the usual rehabilitation training, the patients included in this study receive their allocated programme (FES or control). According to Japanese insurance policy, a 40 min training programme is considered one unit; all the patients undergo one training unit per day over an 8-week interventional period (figure 1). Any rehabilitation programmes initiated before this trial are continued under the condition that intervals, duration or contents remain the same throughout the trial.

FES group (intervention group)

The FES device used in this study is Walkaide (Innovative Neurotronics). The researchers set up the surface electrode onto the proximal region of the lower limb with the cuff. An internal sensor detects leg tilt and determines whether an individual is in the swing or stance

	Screening period		Pre- treatment period	Treatment period	
	Screening assessment	Enrollment and randomization	Baseline assessment		
	Within 7 days prior to enrollment		Within 3 days after randomization	Day 0	Week 8 or at the time of discontinuation
Eligibility screen	X				
Informed consent	X				
Trial-use of FES	X				
Confirmation of eligibility		X			
Enrollment and randomization		X			
Interventions (FES or control)				←	→
Assessments					
6 minute walk test			X		X
10 meter walking speed			X		X
Fugl-Meyer assessment			X		X
Modified Ashworth scale			X		X
Active and passive range of motion for ankle dorsiflexion			X		X
Timed up-and-go test			X		X
Stroke Impact Scale			X		X
Patient reported outcome measure			X		X
Gait evaluation by the care providers (videotaped)			X		X
Evaluation of adverse events	X	X	X	X	X

Figure 2 Study flow. Enrolled patients undergo 1 week of screening period to confirm tolerability and receptivity of FES. FES, functional electrical stimulation.

phase, then stimulates the common peroneal nerve in the swing phase. The stimulation from FES activates the weakened muscle to lift the foot appropriately and, at the same time, assists with recovery by restoring the nerve-to-muscle signals.

The TES (therapeutic electrical stimulation) mode is used in patients with FAC category 3, while the HAND mode (manual electrical stimulation) and TILT mode (electrical stimulation delivered in the swing phase based on a tilt sensor) are used in patients with FAC category 4. Treatment modes are selected and adjusted by qualified programme providers. In the TES mode, electrical stimulation is repeated at regular intervals. This mode is used for muscle stretching and joint range training. The stimulation and pause times for the TES mode are programmed prior to rehabilitation. In the HAND mode, physicians or physical therapists manually control the FES using a hand switch. In TILT mode, FES operates automatically according to the incline of the foot. Walkaide senses the tilt and automatically adjust the mode so that it stimulates the common peroneal nerve to lift the foot at the right time during the gait cycle, prompting a more natural, efficient and safe walking pattern.

The use of AFO is prohibited during the FES training. All the training is overseen by the physician or physical therapists.

Control group

Training is provided to the control group without using the FES. Training for patients with FAC category 3 includes self-stretching and foot dorsiflexion ROM training (triple foot triceps stretch training to extend the foot dorsiflexion ROM); training for patients with FAC category ≥4 includes gait training using an AFO.

Outcomes

The primary outcome measured will be the change in the 6 min walk test (6-MWT) defined as the difference in distance during a 6 min timed walk (metres) barefoot at weeks 0 and week 8. 6-MWT is a feasible measure that is often used to determine functional capacity in individuals with compromised ability and has been shown to be highly reliable in evaluating various aspects of gait performance in individuals with chronic mild to moderate hemiparesis after stroke.[21–23] Secondary outcomes included changes in barefoot gait speed as assessed using the 10 m walk test.[6 24] Walking speed and endurance are two important aspects of walking capacity in patients with stroke. The 10 m walk test is performed at a comfortable walking speed, and the average value of two measurements is calculated.[10 11 25] Also, as secondary outcomes, the 6-MWT and 10 m walk test will be evaluated using WA with AFO, if relevant. In addition, the difference in the total Fugl-Meyer assessment score (only the lower extremity part relevant to this trial) will be evaluated to

assess the physical recovery poststroke. The modified Ashworth scale scores are used to assess spasticity. The Ashworth scale is a widely used clinical measure of joint resistance.[26] The Ashworth scale subjectively grades the manual sensation of mechanical resistance experienced by the examiner during a one second joint rotation over the full ROM. Furthermore, the differences in active and passive ROM for ankle dorsiflexion, timed up-and-go test score (by barefoot, using FES and AFO-assisted, if relevant), the Stroke Impact Scale score, the patient-reported outcome measure and the videotaped gait assessment will be evaluated. Passive and active ankle-dorsiflex on ROM are measured by the physical therapist or physician and are recorded in 5° increments. Stroke Impact Scale covers eight domains: strength, hand function, mobility, activities of daily living, memory, communication, emotion and handicap and is an established instrument to assess stroke recovery.[27 28] The patient-reported outcome measure has been widely used in rehabilitation trials in Japan to capture patient perception of their own health status or quality of life without interpretation by clinician. It consists of three questionnaires: (1) patient-reported burden in raising the foot during bare-foot walking, (2) patient-reported spasticity while walking bare-footed, (3) patient-reported stability in bare-footed walking. Ten-metre walk tests are videotaped and gait disturbance is evaluated by an independent central adjudication committee which comprised of doctors, physical therapists and occupational therapists using the Rivermead Visual Gait Assessment, which is a four-point scale visual gait assessment form validated elsewhere.[29] For safety assessment, any adverse event will be collected regardless of its severity (box 1). All the outcomes are collected at week 0 (pretreatment period) and week 8, except for adverse events which will be collected at any the time of the event.

Study organisation

Periodic assessments of safety and efficacy are performed by an independent Data Monitoring Committee (DMC) composed of three members with appropriate expertise. Project and data management, and data analysis are conducted by the Translational Research Informatics Center for Medical Innovation (http://www.tri-kobe.org/). The monitoring is done centrally to ensure that the randomised cases reach their target number and that the study is executed per protocol. In the case of serious protocol deviation, serious adverse events or safety issues, a site visit may be performed whenever necessary. Audits will be performed to abide by Japanese laws and will follow a discrete Standard Operating Procedure independent from the investigators and the sponsor.

A protocol amendment will be required if there is any change in study design, eligibility criteria, intervention, endpoint, endpoint analyses or targeted event during the study. The amendment will need to be approved by the institutional review board, and the study principal investigator is responsible for communicating changes to institutional investigators, the data monitoring committee, the data centre and the study statisticians.

Sample size estimates

Sample size was calculated based on feasibility. With 200 cases equally randomised to the control and intervention group, a difference of 43.8 m in the 6-MWT is detectable with statistical power of 80%, on the assumption that the SD is 110 m.

Statistical analyses

Patient characteristics will be summarised descriptively for quantitative variables and as a number and percentage for qualitative variables. The change in 6-MWT distance before and after the treatment will be evaluated for all the participants. Analysis of covariance will be performed to compare the change in the 6-MWT distance between the groups and to estimate the adjusted difference and 95% CIs. Covariates included in the analysis will be FAC, age and type of stroke. Since this is a prospective study with central data monitoring system, targeting in-hospital patients, a high proportion of non-adherence cases and/or missing data are unexpected.

Access to the final trial data set and trial results

The authors will have access to the final trial data set; the trial results will be presented to the public at a professional conference and in a peer reviewed journal.

DISCUSSION

This is a multicentre, randomised, open-label, parallel-group study assessing the effectiveness of FES in Japanese patients with hemiplegia convalescing from stroke.

FES has been reported to be effective in improving spasticity in the plantar flexion muscle,[30] enhancing muscular strength and increasing stability by improving lost exercise ability through functionally stimulating residual nerve tract electronically.[18 31] However, most of these studies have been conducted in Western countries, and there is only limited data for non-western countries where differences in life style requires complex and different muscle movements. In this study, we have a unique opportunity to evaluate the efficacy and safety of FES in different settings than previously studied, and our results will provide important information to non-Western countries, such as Japan.

Although the mechanism of FES seems promising, stimulation control and muscle fatigue have been identified as reasons for premature discontinuation, and only few trials are powered to adequately evaluate its effectiveness.[9 32–34] In our study, we have implemented a screening period to confirm the tolerability and receptivity to FES before randomisation to minimise premature discontinuation.

Additionally, our study evaluates the functional outcome which will be useful in interpreting the results. The most frequent adverse event seems to be related to skin problems due to the electrodes. In this study, we will collect

all the information regarding adverse events regardless of the severity to have a full understanding of safety issues. Results from our randomised controlled trial will provide evidence to the optimal poststroke treatment regimens for Japanese patients with FAC 3 or 4 and could impact treatment in other non-Western countries as well.

TRIAL STATUS

Trial registration

The protocol was approved by the Kagoshima University Hospital Institutional Review Board on 8 December 2015 (approval number 27–171). The protocol was finalised on 14 March 2018 and was revised to the current version (V.1.5) on 14 March 2018. The study was registered on 17 January 2016 at the University Hospital Medical Information Network-Clinical Studies Registry (http://www.umin.ac.jp, UMIN000020604). Recruitment began in May 2016 and the first patient was included on 30 August 2016. This study is ongoing and our data are not locked at the time of the submission of this paper.

Ethics and dissemination

Ethics approval and consent to participate

This study is conducted in accordance with the principles of the Declaration of Helsinki and the Ethical Guidelines for Medical and Health Research Involving Human Subjects (Ministry of Education, Culture, Sports, Science and Technology/Ministry of Health, Labour, and Welfare) and is approved by the ethics committee of all participating institutions. All the participants consented to participate in the trial.

SUMMARY AND CONCLUSION

The study compares the efficacy and safety of FES. This is a randomised controlled trial and is expected to provide strong evidence in the field of rehabilitation for patients in the stroke convalescence phase.

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