Clinical Trial CT-2021-CTN-01514-1 v1 Repository

Submission Date: 05/05/2021 Acknowledged by TGA Processed Date: 19/05/2021

Application

Sponsor Name	Neuroscience Research Australia
Sponsor Address	PO Box 1165 RANDWICK NSW 2031
Notification Fee	\$380

Trial Details

Contact Phone Number02 9399 1676Contact Emaild.mckay@neura.edu.auAtternative Contact NameLynne BilstonAlternative Contact Phone Number02 9399 1673Alternative Contact EmailLoliston@neura.edu.auProtocol NumberBILSTON_2021-01Expected Trial Start Date21/01/2026Potential Use of Restricted GoodsNoPotential Use of Restricted GoodsNoTrial TypeDevicePrife Description of TrialInvolves the use of a Medical DeviceTrial TypeDeviceBrief Description of TrialThis trial utilises a gravitational MR elastography transducer to create small vibrations in participants while inside the MR scanner, so that shear wace deformation can be captured during scanning and biomechanical properties inferred.Total Number of Participants to be Enrolled in the Trial TransNeuroscience Research AustraliaSitesSite Physical LocationNeurA, Margarete Ainsworth Building, 139 Barker Street, RandwickState / TerritoryNew South WalesExpected Site Start Date17/05/2021Principal Investigator Contact Phone0293991673Principal Investigator Contact Ph	Contact Name	Deborah McKay
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Approving Authority Contact Position	Chief Executive Officer
Approving Authority Contact Phone	0293991604
Approving Authority Contact Email	p.schofield@neura.edu.au
Medical Devices	
Product Name	Gravitational Transducer for Magnetic Resonance (MR) Elastography
Is this a	Medical Device
Classification	Class 1
Description/Intended Purpose for Medical Device	MR elastography is a non-invasive imaging technique that allows biomechanical properties of in-vivo tissue to be measured by analysing the propagation of low magnitude shear waves in MR images. The shear waves are produced externally by an elastography transducer and felt by participants as small vibrations. The design of the transducer specified in this application uses a rotating eccentric mass to create small vibrations, giving rise to the name "gravitational transducer". The unit comprises two parts; the 'front end' consisting of the transducer itself (a small, rounded, enclosed rectangular unit made of Delrin) and the flexible axis that transmits the rotation towards the transducer (a long PEEK cable housed in rubber); and the 'back end', consisting of the electronics and the motor.Designed and built by Professor Ralph Sinkus's team in the School of Biomedical Engineering & Imaging Sciences at Kings College London, the device is being used internationally at two sites. The design of the gravitational transducer has been optimised to reduce noise in the shear waves when compared to a commercially available, pneumatically driven MR elastography transducer. All components that enter the magnet room of the MR scanner and come into contact with participants are entirely non-magnetic, non-conductive, spill proof, resistant to shocks such as being dropped from the working height, and designed to withstand loads in excess of 100kg. The generated vibration amplitudes are well below safety limits for the vibrational exposure for workers (see Ehman et al., Vibration safety limits for magnetic resonance elastography. Physics in medicine and biology 53, 925-935, 2008). The back-end that drives the transducer is enclosed in a sealed housing protecting users against electric rotor in the front-end becomes blocked, or if the requested vibration frequency exceeds 100Hz. The device will be used to produce vibrations in in-vivo tissues such as skeletal muscle, liver and brain, replacing the electronics in the vibration frequ
Intended Purpose for Trial	Investigational Product
Manufacturer	Biomedical Engineering Department, Kings College London