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 Name	Deborah McKay
Contact Phone Number	02 9399 1676
Contact Email	d.mckay@neura.edu.au
Alternative Contact Name	Lynne Bilston
Alternative Contact Phone Number	02 9399 1673
Alternative Contact Email	l.bilston@neura.edu.au
Protocol Number	BILSTON_2021-01
Expected Trial Start Date	17/05/2021
Expected Completion Date	21/01/2026
Potential Use of Restricted Goods	No
Title of Study	Feasibility study for using a gravitational magnetic resonance (MR) elastography transducer
This Trial	Involves the use of a Medical Device
Trial Type	Device
Brief Description of Trial	This trial utilises a gravitational MR elastography transducer to create small vibrations in participants while inside the MR scanner, so that shear wave deformation can be captured during scanning and biomechanical properties inferred.
Total Number of Participants to be Enrolled in the Trial	51-200
Therapeutic Area	Musculoskeletal System

Sites

Site Name	**Neuroscience Research Australia**
Site Physical Location	NeuRA, Margarete Ainsworth Building, 139 Barker Street, Randwick
State / Territory	New South Wales
Expected Site Start Date	17/05/2021
Principal Investigator Name	Professor Lynne Bilston
Principal Investigator Contact Phone	0293991673
Principal Investigator Contact Email	l.bilston@neura.edu.au
HREC Name	University of New South Wales Executive Committee
HREC Code	EC00142
HREC Contact Officer	Leonne Thompson
HREC Contact Position	Human Research Manager
HREC Contact Phone	0293856222
HREC Contact Email	humanethics@unsw.edu.au
Name of Approving Authority	Neuroscience Research Australia
Approving Authority Contact Officer	Peter Schofield

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 shock. The motor is rigidly fixed to a base plate mounted in an equipment rack to prevent any movement. The system continually monitors the current provided to the motor, and is designed to shut down in the unlikely case that the rotating shaft or eccentric 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 electromagnetic transducer design that we have used previously.
Intended Purpose for Trial	Investigational Product
Manufacturer	Biomedical Engineering Department, Kings College London