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Acupuncture for Established Stroke

Submission date 30/09/2004	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 30/09/2004	**Overall study status** Completed	
Last Edited 29/10/2012	**Condition category** Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0203092386

Study information

Scientific Title

Study objectives
Is manual acupuncture superior to sham manual acupuncture for improving the recovery from stroke in respect of functional and psychological status when given to established cases? The objectives of this study are to compare the changes of outcomes of stroke patients between baseline and post-treatment, and 6 months follow up.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled clinical trial with 2 parallel arms

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Cardiovascular: Stroke

Interventions
152 chronic stoke patients will be invited to participate. They will be randomly divided to manual acupuncture group and sham acupuncture group and will be given 12 manual acupuncture treatments (tailored by constitution) in 12 weeks. All subjects will be assessed 3 times: baseline assessment before randomisation, post-treatment, and 6 month follow-up.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Primary outcome of this study is changes of Action Research Arm Test between baseline and post-treatment. Data will be analysed by statistical procedure like the Mann-Whittney test.

Secondary outcome measures
Other outcome measures are Fugl-Meyer Assessment Scale, Ashworth spasticity Scale, 9-hole peg test, Timed 10-metre walk, and EuroQoL.

Overall study start date
15/01/2001

Completion date
31/03/2004

Eligibility

Key inclusion criteria
1. All patients of any age with stroke due to infarction or haemorrhage at any brain location scanned computed tomography (CT) or magnetic resonance imaging (MRI)
2. Physically capable of travelling to hospital for treatment
3. Giving informed consent.

Participant type(s)
Patient

Age group
Not Specified

Sex
Both

Target number of participants
152

Key exclusion criteria
1. Patients who do not have capacity to communicate and give consent
2. History of serious diseases such as cancer, auto-immune disease and Acquired Immunodeficiency Syndrome (AIDS)
3. Fear of needling
4. History of surgery under general anaesthetic within 6 months
4. Major bleeding diseases

Date of first enrolment
15/01/2001

Date of final enrolment
31/03/2004

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Exeter
Exeter
United Kingdom
EX2 4NT

Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Government

Funder Name
Royal Devon and Exeter NHS Trust

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	26/09/2005		Yes	No