Acupuncture for Established Stroke

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

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number 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

Study type(s)

Treatment

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(s)

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.

Key secondary outcome(s))

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

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

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Αll

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

United Kingdom

England

Study participating centre University of Exeter

Exeter United Kingdom EX2 4NT

Sponsor information

Organisation

Department of Health

Funder(s)

Funder type

Government

Funder Name

Royal Devon and Exeter NHS Trust

Results and Publications

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