

Acupuncture for Established Stroke

Submission date 30/09/2004	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 30/09/2004	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 29/10/2012	Condition category Circulatory System	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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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 stroke 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