A pilot study for a randomised controlled trial to determine if reflexology can help improve neurological damage caused by taxane chemotherapy drugs

Submission date 30/09/2004	Recruitment status No longer recruiting	 Prospectively registered Protocol
Registration date 30/09/2004	Overall study status Completed	 Statistical analysis plan Results
Last Edited 09/11/2015	Condition category Cancer	Individual participant dataRecord updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s) Scientific

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

Study information

Scientific Title

A pilot study for a randomised controlled trial to determine if reflexology can help improve neurological damage caused by taxane chemotherapy drugs

Study objectives

Does reflexology help to improve the neurotoxicity (tingling and numbness) in the hands and feet experienced by some patients following cytotoxic chemotherapy with Paclitaxel and Docetaxel?

Can the benefits of using reflexology in this setting be proven by the use of nerve conduction studies? (i.e. will there be a statistical difference over time in the reflexology group compared to the control group?).

Does the use of reflexology in this context help patients to feel better in themselves? (Quality of Life questionnaire will be used for this).

Ethics approval required

Old ethics approval format

Ethics approval(s) Not provided at time of registration

Study design Randomised controlled trial

Primary study design Interventional

Secondary study design Randomised controlled trial

Study setting(s) Not specified

Study type(s) Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Neurotoxicity after chemotherapy

Interventions

Single centre, patient volunteers, prospective, controlled, therapeutic, observational, randomised, questionnaire study.

Reflexology vs no reflexology

Intervention Type Other

Phase Not Specified

Primary outcome measure Not provided at time of registration

Secondary outcome measures Not provided at time of registration

Overall study start date 01/06/2003

Completion date 01/06/2004

Eligibility

Key inclusion criteria Not provided at time of registration

Participant type(s) Patient

Age group Not Specified

Sex Not Specified

Target number of participants Total of 40 patients required for reflexology and control groups, 20 for each arm of the study.

Key exclusion criteria Not provided at time of registration

Date of first enrolment 01/06/2003

Date of final enrolment 01/06/2004

Locations

Countries of recruitment

England

United Kingdom

Study participating centre City Hospital Birmingham United Kingdom B18 7QH

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 Sandwell and West Birmingham Hospitals NHS Trust (UK)

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