

An observational study on the effect of acupuncture with electric stimulation in multiple sclerosis patients with bladder dysfunction.

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The research question which needs to be answered is: Is it feasible to recruit in 6 months a minimal of 20 patients with MS and bladder dysfunction to participate in an acupuncture study and are these patients compliant with the treatment and the...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Demyelinating disorders
Study type	Observational invasive

Summary

ID

NL-OMON31325

Source

ToetsingOnline

Brief title

Acums

Condition

- Demyelinating disorders
- Bladder and bladder neck disorders (excl calculi)

Synonym

bladder dysfunction, urine incontinence

Research involving

Human

Sponsors and support

Primary sponsor: Multiple Sclerose Centrum Nijmegen

Source(s) of monetary or material Support: ZONMw, Nederlandse artsen acupunctuur vereniging

Intervention

Keyword: acupuncture, bladder dysfunction, multiple sclerosis, quality of life

Outcome measures

Primary outcome

Primary outcome parameters for the feasibility of the study are:

- percentage of eligible patients that are willing to have electroacupuncture
- reasons for refusal to participate
- percentage of patients who are compliant with record keeping for the 3-day bladder diary
- reasons for drop out during the study

Secondary outcome

Secondary outcome parameter relating to the effectiveness of the electroacupuncture:

- patients' perceptions of improvement of their quality of life determined by the I-QOL instruments.
- Reduction in the frequency of voiding, number of incontinent episodes, severity of incontinence, number of nocturia episodes and urgency, over 3 days determined by the 3-day bladder diary
- The severity of the incontinency will be measured in by the number of pads used, (daily registering of number of pads)

Study description

Background summary

In patients with Multiple Sclerosis (MS), bladder dysfunction is a common problem that affects up to 80% of the patients. Failure to store urine (detrusor hyperreflexia) (DS), failure to empty urine (detrusor-sphincter dyssynergia) (DSS) or a combined dysfunction leads to voiding dysfunction. The complaints vary from an increased frequency to void, a desperate urgency to empty the bladder and urinary leakage. The consequences are lowered self-image, social isolation, loss of productivity and loss of quality of life.

Urine-retention can lead to an increased risk of urinary tract infection (UTI) which can lead to a deterioration of the MS. Current treatment like anticholinergic medication, behavioural therapy and physical therapy are partially effective. Medication has substantial adverse effects like dry mouth and often leads to a low compliance. Catheterisation, though effective, is at the expense of quality of life. Intravesical electro stimulation is costly and can have many complications like infection or battery failure with another surgical intervention as consequence. Several studies have supported the effectiveness electroacupuncture (electrical stimulation on acupuncture needles) on voiding dysfunction. Tuzuner et al (1989) and Blorkstrom (2000) treated children with enuresis nocturna with positive results. Furthermore, electrical stimulation of the acupuncture point SP 6, known as percutaneous tibial stimulation was effective with regard to the voiding dysfunction and the quality of life. However, most of the studies included a heterogeneous group of patients, including non-neurological bladder-dysfunction. This raises the question what the effect will be in a homogenous group of patients with neurological bladder dysfunction.

Study objective

The research question which needs to be answered is: Is it feasible to recruit in 6 months a minimal of 20 patients with MS and bladder dysfunction to participate in an acupuncture study and are these patients compliant with the treatment and the primary outcome measurements?

Study design

The feasibility of the study will be evaluated by an observational study.

Study burden and risks

The burden consists of a screening visit to the centre where a bladder scan will be done and a urine study. Moreover, a questionnaire has to be filled in and a bladder diary has to be registered during 3 days. It takes about 10 minutes to

fill in the questionnaire and about 15 minutes a day for the bladder diary. Then, 10 treatments, once a week will take place at the practice of the treating acupuncturist. 4 Needles will be placed in the legs and connected to a electro-stimulation device. Sometimes, the needles can hurt a little or there may occur a bruising. Treatment takes about half an hour. At the end of the treatment the question3-day bladder diary has to be filled in again. The risks of the acupuncture treatment are minimal.The practices (a total of one per centre) are selected near by the centre so traveling time will be as short as possible.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

Patients with MS and voiding complaints during at least 6 months: greater than 8 voids per

day, subjective urgency to void and urge-associated incontinence at least twice during a 3-day period of time.

Exclusion criteria

bladder infection at baseline, post voiding residual volume more than 100 ml, bladder complaints less than 6 months, a relapse less than 30 days before screening, complaints of spasms; pregnancy; sacral neurostimulator implanted, severe cardiopulmonary disease, unable to complete a 3-day voiding diary or the questionnaire.

Study design

Design

Study phase:	4
Study type:	Observational invasive
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	10-09-2007
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO	
Date:	30-06-2007
Application type:	First submission
Review commission:	IRB Amsterdam: Independent Review Board Amsterdam (Amsterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL17705.003.07