A randomised controlled trial comparing physiotherapy to electromagnetic stimulation for urinary incontinence

Published: 14-01-2014
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Primary objective:Subjective improvement of urinary incontinence (PGI-I)Secondary objectives:Objective (using stress test, padtest, bladder diaries, Sandvik score) and subjective cure of incontinence (questionnaires)Complicaties en de novo...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bladder and bladder neck disorders (excl calculi)
Study type	Interventional

Summary

ID

NL-OMON38783

Source
ToetsingOnline

Brief title
The PIE study

Condition

- Bladder and bladder neck disorders (excl calculi)

Synonym
urinary loss

Research involving
Human

Sponsors and support

Primary sponsor: Isala Klinieken
Source(s) of monetary or material Support: geen sponsor /subsidie financiering

Intervention

Keyword: electromagnetic stimulation, physiotherapy, Stress (predominant) urinary incontinence, Urge (predominant) urinary incontinence

Outcome measures

Primary outcome

Primary objective:

Subjective improvement of urinary incontinence (PGI-I)

Secondary outcome

Secondary objectives:

Objective (using stress test, padtest, bladder diaries, Sandvik score) and

subjective cure of incontinence (questionnaires)

Complicaties en de novo urogenital symptoms

Effect on defaecation (questionnaires)

Effect on dyspareunia (questionnaires)

Discomfort of treatment (VAS Scores)

Cost/ effectiveness analysis

Study description

Background summary

Conservative treatment of urinary incontience is our first choice.
Studies have shown that physiotherapy can be uncomfortable due to insertion of various vaginal devices.
A large number patients receive further treatment after completing physiotherapy or bladder training due to insufficient effect.
Electromagnetic stimulation is an existing treatment, but not widely used and has shown variable results in previous studies. The QRS PelviCenter is a new version of the pre-existing electromagnetic chair. Advantages include no physical contact and optimal effect may be seen sooner, namely after 6 weeks

versus 3-6 months with physiotherapy/ bladder training.

Study objective

Primary objective:
Subjective improvement of urinary incontinence (PGI-I)

Secondary objectives:
Objective (using stress test, padtest, bladder diaries, Sandvik score) and subjective cure of incontinence (questionnaires)
Complicaties en de novo urogenital symptoms
Effect on defaecation (questionnaires)
Effect on dyspareunia (questionnaires)
Discomfort of treatment (VAS Scores)
Cost/ effectiveness analysis

Study design

Monocentre prospective study consisting of 2 trials, namely one for patients with urge urinary incontinence who will be randomised between bladder training or electromagnetic chair and secondly one for patients with stress urinary incontinence who will then be randomised between physiotherapy or electromagnetic chair.

Intervention

Physiotherapy / bladdertraining versus electromagnetic stimulation

Study burden and risks

De belasting welke het onderzoek met zich meebrengt voor de patient bestaat uit het invullen van vragenlijsten en het uitvoeren van padtests. Indien patiente loot voor electromagnetische stimulatie 18 behandelsessies op de polikliniek in het ziekenhuis. Indien patiente loot voor fysiotherapie of blaastraining (standaard behandeling): geen extra ziekenhuis bezoeken.

The burden of the study for the patiente will be completing questionnaires and padtests. When the patient randomises for electromagnetic stimulation 18 treatment sessions at outpatient clinic. If the patient randomises for physiotherapy or bladdertrainign (standard treatment): no extra hospital visits.

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

urinary incontience

Exclusion criteria

Metal or electronic inplants
Pregnancy
Cardiac arrhythmia
Neurological disease
History of anti-incontinece surgery
Pelvic malignancy
History of pelvic radiotherapy

Physiotherapy for incontinence in the last 6 months

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-08-2018
Enrollment:	240
Type:	Actual

Medical products/devices used

Generic name:	QRS Pelvicenter
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	14-01-2014
Application type:	First submission
Review commission:	METC Isala Klinieken (Zwolle)

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	NL46289.075.13