Pilot study for the project: A randomized clinical trial of urinary incontinence in older women: cost-effectiveness of protocolized assessment and evidence based treatment

Published: 22-12-2006
Last updated: 14-05-2024

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Genitourinary tract disorders NEC
Study type	Observational non invasive

Summary

ID

NL-OMON30406

Source
ToetsingOnline

Brief title
Pilot urinary incontinence in elderly women

Condition

- Genitourinary tract disorders NEC

Synonym
involuntary loss of urine, urinary incontinence

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: elderly women, family practice, quality of life, urinary incontinence

Outcome measures

Primary outcome

In the pilot the recruitment procedure is studied, the quality of the data from

the questionnaires and the micturition diary and the logistics of the

urogynaecological examination. Also, the time investment is measured.

Secondary outcome

niet van toepassing

Study description

Background summary

Many elderly women with involuntary loss of urine go undiagnosed and untreated. Proven effective treatments are underused. There is a lack of data on the cost-effectiveness of an active, protocolized assesment and evidence based treatment of urinary incontinence. That is why a preliminary application is made with ZonMW for a randomized clinical trial of urinary incontinence in elderly women.
A pilot study is needed to study the recruitment of patients and the diagnostic pathway in general practice and at the outpatient department for pelvic floor studies of the UMCG.

Study objective

The objective of the pilot study is to get information on the recruitment of patients, the filling in of the questionnaires, the micturition diary, the course of and information from the interview and about the logistics of the urogynaecological examination.
With these data the intervention in the experimental group of patients can be

planned optimally. In the pilot study special attention is paid to the impact of the diagnostic pathway for the patient, teh quality of the data from the questionnaires and the time needed for the urogynaecological examination

Study design

The pilto study has an observational design. The diagnostic pathway is tested that will be followed by patients who wiil be randomized into the intervention group in the future randomized trial.

Study burden and risks

The subjects in the study population do not run any risk from the investigations as all tests are non-invasive. The burden of the study consists of the filling in of questionnaires, the answering of questions in the interview and the participation in a urogynaecological examination.

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

Women 55 years or older
Suffering from urinary incontinence: involuntary loss of urine two or more times a month
Able to fill in a questionnaire
Informed consent

Exclusion criteria

Indwelling urinary cateter
Urogynaecological malignancies
Demented
Poor physical condition

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	02-01-2007
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO Date:	22-12-2006
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL15480.042.06