A randomised controlled trial comparing the clinical and cost-effectiveness of pelvic floor muscle exercise versus TVT(O) procedure for female moderate to severe stress urinary incontinence

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20079

Source
NTR

Brief title
PORTRET Trial

Health condition

stress urinary incontinence, SUI, TVT, TVT-O, PFMT

Sponsors and support

Primary sponsor: University Medical Center Utrecht (UMCU)
Source(s) of monetary or material Support: ZonMw The Netherlands Organization for Health Research and Development

Intervention

Outcome measures

Primary outcome

Complete cure on objective and subjective parameters

Secondary outcome

1. The incremental cost-effectiveness of TVT as compared to PFMT, accounting for direct and indirect costs parameters.

2.Subjective improvement in general and disease-specific quality of life.

3.Complications and de novo urogenital symptoms.

4.Development of a prediction model for successful treatment, with the therapy given (PFMT or TVT) as independent variable in the model.

Study description

Background summary

OBJECTIVE: To compare the clinical and cost-effectiveness of pelvic floor muscle training versus TVT-O)-surgery as primary treatment of moderate to severe female urinary incontinence.

STUDY DESIGN: Multi-centre randomised controlled trial.

STUDY POPULATION: Women with moderate to severe, predominantly stress, urinary incontinence,
who have not received specialised PFMT or previous anti-incontinence surgery.

INTERVENTIONS: Women will be assigned to either PFMT by a specialised physiotherapist for a standard of 9-18 session in a period of 6 months, or TVT(O)- surgery.

OUTCOME MEASURES: Objective cure will be assessed from history and clinical parameters. Subjective improvement will be measured by generic and disease-specific quality of life instruments. A prediction model for a successful outcome will be developed.

SAMPLE SIZE CALCULATION / DATA ANALYSIS: In order to observe a significant difference insubjective improvement, 65% in PFMT and 80% in TVT®, with a power of 0.9, a total of 200 women have to be assigned by randomisation to each group.

ECONOMIC EVELUATION: The short term (1 year) incremental cost-effectiveness in terms of

costs per additional year free of urinary incontinence and costs per QALY gained will be estimated. As the vast
majority of relevant outcomes will have occurred by one year this period appears sufficient. Uncertainty will be evaluated using bootstrap techniques (1000 replicates) on the individual patient data. A CEA plane will be used to depict the dispersion of the estimates of incremental costs and effects of TVT(O) compared to PFMT, thus allowing a direct inference with regard to the certainty of one treatment having a more favourable balance between costs and effects over the other.

TIME SCEDULE: We estimate
that the inclusion will be finished within 18 months. PFMT may take up to 6 months to be regarded as optimal, leaving 12 months for follow-up after treatment ending.

Study objective

To compare the clinical and cost-effectiveness of pelvic floor muscle training versus TVT/TVT-O surgery as primary treatment of moderate to severe female urinary incontinence.

Study design

0= randomisation

2 months

4 months

6 months

12 months

18/24 months

Intervention

Women will be assigned to either PFMT by a specialised physiotherapist for a standard of 9-18 session in a period of 6 months, or TVT(O) surgery.

Contacts

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Eligibility criteria

Inclusion criteria

1. All women aged 35-80 years who present with symptoms of moderate to severe, predominant stress urinary incontinence.

2. Moderate to severe stress incontinence according to the Sandvik severity index. The index is calculated by multiplying the reported frequency (four levels, 1 to 4) by the amount of leakage (two levels, 1 and 2). The resulting index value (1-8) is further categorized into slight (1-2), moderate (3-4) and severe (5-8)

3. Objective confirmation of stress urinary incontinence by either examination, stress-test or urodynamics.

Exclusion criteria

1. A post voiding bladder volume of more than 100 ml.

2. History of anti-incontinence surgery.

3. PFMT exercises by a specialised physiotherapist for urinary incontinence in the previous 6 months.

4. Genital prolapse Stage 2 or more according to the POP-Q classification.

5. Probability of future pregnancy and childbirth present.

6. Co morbidity which is associated with increased surgical risks, for instance women with ASA 3 or 4 classification.

7. History of recurrent lower urinary tract infection (> 3 times/year).

8. Insufficient knowledge or understanding of the Dutch language.

9. Use of medication interacting in bladder function.

10. History of or current major psychiatric illness.

11. History of chronic neurological disease.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-01-2008
Enrollment:	400
Type:	Anticipated

Ethics review

Positive opinion

Date:	13-03-2008
Application type:	First submission

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
NTR-new	NL1203
NTR-old	NTR1248
Other	ZonMw : 80-82310-98-08203
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A