Transurethral Ultrasound directed Injection of autologous Myoblasts, Fibroblasts and Collagen for the treatment of urinary incontinence

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Ethical review	Approved WMO
Status	Will not start
Health condition type	Bladder and bladder neck disorders (excl calculi)
Study type	Interventional

Summary

ID

NL-OMON29996

Source
ToetsingOnline

Brief title
Urocell in urinary incontinence

Condition

- Bladder and bladder neck disorders (excl calculi)
- Renal and urinary tract therapeutic procedures

Synonym
involuntary urine loss, stress-incontinence

Research involving
Human

Sponsors and support

Primary sponsor: Innovacell Biotechnologie GmbH
Source(s) of monetary or material Support: Mrace;Innovacell

Intervention

Keyword: autologous myoblasts, fibroblasts, stress incontinence, urinary incontinence, Urocell

Outcome measures

Primary outcome

Improvement of the urinary incontinence score.

Secondary outcome

- Urodynamics: function of the urinary vesicle and the urethral closure

pressure pre- and post-therapy.

- Sonography and elastography of the urethra: the urethra, contractility of the

rhabdosphincter, thickness and morphology of the rhabdosphincter before and

after therapy.

- Contilife questionnaire

Study description

Background summary

Urinary incontinence is a frequent health problem. The contribution of stress incontinence to the overall prevalence of incontinence is major, especially in women. An age-related weakening of the sphincter muscle is the most frequent cause for urinary incontinence, but also traumatisation of this structure due to operations or child delivery play the main role. Up to now, a satisfying solution of the problem * for the patient as well as the physician * was not

generally achievable. Most methods led to inefficient or only short-time results, or were incriminated by unacceptable side effects.

Because incontinence has a major impact on the (socially) functioning of patients, it is important to develop a treatment which results in normal (socially) functioning of patients. With this research and other (already finalised) researches with Urocell we hope to show that the Urocell-method is a new, minimally invasive and patient friendly treatment for the causal and effective treatment of stress incontinence.

Study objective

The objective of the study is to ascertain whether the high effect sizes obtained in the previous studies can be explained according to our working hypothesis, i.e. whether the intervention with Urocell is associated with a structural regeneration and volume increase of the rhabdosphincter muscle and/or the urethral submucosa.

Study design

This study is a prospective, open, multicenter study in patients with stress incontinence.

Intervention

A onetime ultrasound-directed intramuscular and intraurethral injection of Urocell. Urocell is a body*s own product existing of autologous myoblasts and fibroblasts and collagen. The purpose of the treatment with Urocell is improving the urinary incontinence by means of causal therapy in patients with stress incontinence. Secondarily, the aim is an improved quality of life score.

Study burden and risks

Till August 2006, 250 patients with stress incontinence were treated with the product Urocell. In these patients very good results were accomplished. No immediate or chronic unwanted effects were observed.

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

* Age 18-70 years
* Verified diagnosis of urinary incontinence
* Stress- or mixed urinary incontinence (without severe descensus of pelvic organs or dominant urgency complaints)

Exclusion criteria

* A neurological disorder as the sole reason for the incontinence
* Women with marked descensus of the pelvic organs or marked hypermobility of the urethra
*Pregnancy
* Allergy against collagen
* (Planned) treatment with immunosuppressive medication or any immunosupression therapy
* Previous X-ray treatment of pelvic organs
* Severe autoimmune disease
* Bladder instability and/or pure urge incontinence
* Lactating patients
* Previous treatment with TVT, TOT or bulking agents
* Malignancy treated or apt to be treated by x-ray therapy or chemotherapy

Study design

Design

Study phase:	3
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	25
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Generic name:	Somatic cells autologous

Ethics review

Not approved

Date:	07-11-2006
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)

Approved WMO

Date:	09-11-2006
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)

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
EudraCT	EUCTR2006-003214-17-NL
CCMO	NL12342.000.06