# Autologous myoblasts and fibroblasts versus collagen for treatment of stress urinary incontinence in women: a randomised trial

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### Plain English summary of protocol

Not provided at time of registration

### Contact information

### Type(s)

Scientific

### Contact name

Prof Georg Bartsch

### Contact details

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# Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers 2002/42-21

# Study information

### Scientific Title

### **Study objectives**

Incontinence can be better treated with ultrasound-guided application of autologous cells than with standard endoscopic collagen injectons.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Austrian Ministry of Health. Date of approval: 27th August 2002 (ref: GZ 2.481.159/1-VI/A/4/02)

### Study design

Prospective randomized controlled trial.

### Primary study design

Interventional

### Secondary study design

Randomised controlled trial

### Study setting(s)

Not specified

### Study type(s)

Treatment

### Participant information sheet

### Health condition(s) or problem(s) studied

Urinary incontinence

### Interventions

Transurethral ultrasound guided injection of autologus myo- and fibroblasts versus transurethral endoscopic injection of collagen.

### Intervention Type

Other

### Phase

**Not Specified** 

### Primary outcome measure

The following were assessed pre-operatively and 3 and 12 months post-operatively:

- 1. Incontinence score
- 2. Ultrasound parameters

### Secondary outcome measures

The following were assessed pre-operatively and 3 and 12 months post-operatively:

- 1. Quality of life
- 2. Urodynamic parameters

### Overall study start date

01/09/2002

### Completion date

12/05/2005

# **Eligibility**

### Key inclusion criteria

- 1. Women who were admitted to Department of Urology, Medical University of Innsbruck, Austria with stress incontinence.
- 2. Aged between 35 and 85 years

### Participant type(s)

Patient

### Age group

Adult

### Sex

Female

# Target number of participants

63 women

### Key exclusion criteria

- 1. Marked hypermobility
- 2. Urge incontinence

### Date of first enrolment

01/09/2002

### Date of final enrolment

12/05/2005

# Locations

### Countries of recruitment

Austria

# Study participating centre Department of Urology

Innsbruck

# Sponsor information

### Organisation

Medical University of Innsbruck, Department of Urology (Austria)

### Sponsor details

Anichstrasse 35 Innsbruck Austria 6020 hannes.strasser@uibk.ac.at

### Sponsor type

University/education

### **ROR**

https://ror.org/054pv6659

# Funder(s)

### Funder type

Industry

### Funder Name

Innovacell Biotechnologie (Austria)

### **Funder Name**

FWF Austrian Science Fund (Fonds zur Foerderung der wissenschaftlichen Forschung) (ref: P-12828)

## **Results and Publications**

# Publication and dissemination plan

Not provided at time of registration

### Intention to publish date

# Individual participant data (IPD) sharing plan

**IPD sharing plan summary**Not provided at time of registration

# Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	Results	30/06/2007		Yes	No