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

**Submission date**
19/06/2007

**Recruitment status**
No longer recruiting

**Registration date**
16/07/2007

**Overall study status**
Completed

**Last Edited**
03/10/2008

**Condition category**
Urological and Genital Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

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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

Austria
6020

# Sponsor information

**Organisation**
Medical University of Innsbruck, Department of Urology (Austria)

**Sponsor details**
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**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 |