ISRCTN71247587 https://doi.org/10.1186/ISRCTN71247587

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

Protocol serial number
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)

Primary study design
Interventional

Study design
Prospective randomized controlled trial.

Study type(s)
Treatment

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(s)
The following were assessed pre-operatively and 3 and 12 months post-operatively:
1. Incontinence score
2. Ultrasound parameters

Key secondary outcome(s)
The following were assessed pre-operatively and 3 and 12 months post-operatively:
1. Quality of life
2. Urodynamic parameters

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

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

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)

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

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