

# A Prospective Randomized Double-Blind Study on Prevention of Urethral Restenosis by Radiotherapy

<b>Submission date</b> 07/09/2005	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 11/01/2006	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 12/01/2006	<b>Condition category</b> Urological and Genital Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

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

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

## Study information

**Scientific Title**

**Acronym**

RADIUS

**Study objectives**

Postoperative endourethral radiotherapy after urethrotomy may reduce rate of restenosis

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Not provided at time of registration

**Study design**

Randomised controlled trial

**Primary study design**

Interventional

**Study type(s)**

Prevention

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

Urethral stenosis

**Interventions**

Internal urethrotomy followed by postoperative single shot endourethral Ir-192- High Dose Rate (HDR)-brachytherapy within 24 hours. The prescribed dose is 15 Gy/2 mm depth. The control group receives sham brachytherapy.

**Intervention Type**

Other

**Phase**

Not Specified

**Primary outcome(s)**

Prevention of urethral restenosis after internal urethrotomy by radiotherapy

**Key secondary outcome(s)**

Toxicity

**Completion date**

01/02/2006

**Eligibility**

**Key inclusion criteria**

1. Peak flowrate <15 ml/s
2. Age >30

3. Stenosis suitable for internal urethrotomy

4. Written consent

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

Male

**Key exclusion criteria**

1. Prior radiotherapy in this area (penis, prostate, bladder)
2. Cancer of the prostate or urethra or bladder
3. Congenital stenosis
4. Greater than three prior urethrotomies
5. Traumatic genesis
6. Stenosis >2 cm

**Date of first enrolment**

01/02/2005

**Date of final enrolment**

01/02/2006

**Locations**

**Countries of recruitment**

Germany

**Study participating centre**

Klinik für Strahlentherapie

Düsseldorf

Germany

40225

**Sponsor information**

**Organisation**

University of Düsseldorf (Germany)

**ROR**

<https://ror.org/024z2rq82>

**Funder(s)****Funder type**

University/education

**Funder Name**

University of Düsseldorf (Germany)

**Results and Publications****Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration