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

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

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

Protocol serial number N/A

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