

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

Submission date 07/09/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 11/01/2006	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 12/01/2006	Condition category 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

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Prevention

Participant information sheet

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 measure

Prevention of urethral restenosis after internal urethrotomy by radiotherapy

Secondary outcome measures

Toxicity

Overall study start date

01/02/2005

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

Age group

Adult

Sex

Male

Target number of participants

180

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

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Sponsor information

Organisation

University of Düsseldorf (Germany)

Sponsor details

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Sponsor type

University/education

ROR

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

Funder(s)

Funder type

University/education

Funder Name

University of Düsseldorf (Germany)

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