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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
Dr Stephan Gripp

Contact details
Klinik für Strahlentherapie
Universitätsklinikum Düsseldorf
Moorenstrasse 5
Düsseldorf
Germany
40225
+49 (0)2118118992
Gripp@uni-duesseldorf.de

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
40225

Sponsor information

Organisation
University of Düsseldorf (Germany)

Sponsor details
Klinik für Strahlentherapie
Universitätsklinikum Düsseldorf
Moorenstrasse 5
Duesseldorf
Germany
40225
+49 (0)2118118992
Gripp@uni-duesseldorf.de

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