Prevention of Acute Radiation cystitis by using Intra-vesical chondroitin Sulphate.

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The primary objective of this study is to evaluate whether preventive intravesical instillations with 0.2% chondroitin sulphate solution reduce bother related to acute radiation cystitis symptoms patients undergoing pelvic radiotherapy.

Ethical review	Approved WMO
Status	Pending
Health condition type	Bladder and bladder neck disorders (excl calculi)
Study type	Interventional

Summary

ID

NL-OMON36593

Source
ToetsingOnline

Brief title
PARIS

Condition

- Bladder and bladder neck disorders (excl calculi)

Synonym
irradiationlesion of the bladder

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W,Pohl Boskamp

Intervention

Keyword: Cystitis, Intravesical, Prevention, Radiation

Outcome measures

Primary outcome

The difference in Overactive Bladder domain score of the Urogenital Distress Inventory (UDI), as measured 12 weeks after the patient received the first instillation, between the intervention and control group

Secondary outcome

Cost-efficiency of intravesical instillations with 0.2% chondroitin sulphate solution to patients undergoing pelvic radiotherapy for cervical cancer

Study description

Background summary

About 20-25% of the female patients undergoing pelvic radiotherapy suffer from symptoms related to acute radiation cystitis. These symptoms, involving frequent micturition, urgency, nocturia, and urge-incontinence, are known to negatively affect quality of life. Apart from that, treatment of these symptoms carries considerable costs. Therefore we think it is important to try to prevent this condition.

Study objective

The primary objective of this study is to evaluate whether preventive intravesical instillations with 0.2% chondroitin sulphate solution reduce bother related to acute radiation cystitis symptoms patients undergoing pelvic radiotherapy.

Study design

Multi-centre double-blind randomised placebo controlled intervention study

Intervention

Weekly intravesical instillations with 0.2% chondroitin sulphate solution or physiologic sodium chloride solution during the time of radiotherapy (mostly six weeks). The intervention group will be instilled with 0.2% chondroitin sulphate solution and the control group with physiologic sodium chloride solution.

Study burden and risks

Before randomisation patients fill in the questionnaire concerning micturition symptoms and the effects on the quality of life. During the period of radiotherapy patients will fill out a voiding diary (exept the days that they might get chemotherapy).
Participating women will visit the (outpatient) gynaecology clinic weekly to get the intravesical instillation. In week 4 and 12 after randomisation they fill in the questionnaire.

The benefit of participating is that symptoms of radiation cystitis might be prevented.

A pilotstudy showed that the instillations were well tolerated. No severe adverse effects were reported.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Women undergoing primary or adjuvant pelvic radiotherapy for cervical cancer
- Aged 18 years or older
- Able to complete a Dutch questionnaire
- Written informed consent

Exclusion criteria

- Previous surgery of the lower urinary tract
- (Supra-pubic) catheter in situ
- Intermittent catheterisation because of bladder retention
- Intravesical treatment * 6 months prior to inclusion
- Urinary tract infection * 60 days prior to inclusion

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Prevention

Recruitment

NL
Recruitment status: Pending

Start date (anticipated):	01-04-2011
Enrollment:	140
Type:	Anticipated

Ethics review

Approved WMO
Application type:	First submission
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL35108.018.11