Is Uracyst effective to prevent or reduce acute radiation cystitis in patients who are treated with radiotherapy for gynaecologic malignancy?

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The goal of the study is to find out whether micturition complaints are prevented or reducted by the bladder instillations with Uracyst and secondly if it has a positive effect on painscores and micturition related quality of life.

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

Summary

ID

NL-OMON31418

Source
ToetsingOnline

Brief title
Uracyst-RC

Condition

- Bladder and bladder neck disorders (excl calculi)
- Obstetric and gynaecological therapeutic procedures

Synonym
acute radiation cystitis, inflammatory disease of the bladder caused by radiotherapy

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: Gynaecologic malignancy, intravesical chondroitin sulphate, Radiation cystitis, Radiotherapy

Outcome measures

Primary outcome

The primary outcomes are micturition frequency and bladdervolume

Secondary outcome

secondary outcomes are the burden of instillation, painscores and micturition

related quality of life

Study description

Background summary

Women with a gynaecologic malignancy, who are treated with external and internal radiotherapy can suffer from side-effects of the treatment. All patients will have complaints of acute radiation cystitis and around 25% more severely. This is in most cases a self-limiting condition, and apart from painkilling there is no treatment.
Whether quality of life is diminished by these symptoms in this group of patients undergoing a heavy treatment-regimen is unknown. In literature however there is evidence that over-active bladder complaints have a negative influence on the quality of life.
For reduction of symptoms in interstitial cystitis intravesical chondroitin sulphate solution has been effective. In this condition the glucosaminoglycan (GAG) layer in the bladder has been damaged. This makes the urothelium more permeable, which causes overstimulation of the afferent innervation of the bladder and following that symptoms of cystitis occur. This etiology seems also probable in acute radiation cystitis, where the urothelium, which produces the GAG-layer, is damaged by the radiotherapy.

Study objective

The goal of the study is to find out whether micturition complaints are prevented or reducted by the bladder instillations with Uracyst and secondly if it has a positive effect on painscores and micturition related quality of life.

Study design

an open-label pilot study

Intervention

It is our intention to perform bladder instillations, with intravesical chondroitin sulphate 0.2% solution, Uracyst®-s, in 10 patients. Questionnaires concerning micturition-, pain- and quality of life-characteristics and burden of treatment are filled in before the start of the radiotherapy and during 8 weeks after that. The treatment takes 5 to 7 weeks of radiotherapy in total. Ten patients who refuse to undergo the instillation, but agree to fill in the questionnaires, complete them at the same moments during the treatment.

Study burden and risks

extra visit on the gynaecologic department: only applicable for patients not receiving chemotherapy: 12 hours in total
catheterisation: patient dependent: low to moderate burden; low risk of urinary tract infection
postpone micturition during instillation: low to moderate burden
allergic reaction: very low risk

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

Female * 18 years of age;
Cervical cancer FIGO stage IIB-IIIB/ cervical cancer FIGO stage IB-IIA needing adjuvant (chemo-) radiotherapy/ endometrial cancer with (adjuvant) radiotherapy;
Must provide a signed informed consent.

Exclusion criteria

History of previous procedure(s) (e.g., augmentation cystoplasty, cystectomy or cystolysis), diseases or infections of the bladder or urethra that has affected bladder function;
Urinary tract infection * 90 days prior to baseline;
Participated in another clinical study with an investigational drug or device * 30 days prior to baseline.

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-06-2007
Enrollment:	20
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	Uracyst®-s
Generic name:	sodium chondroitin sulphate
Registration:	Yes - NL intended use

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
EudraCT	EUCTR2007-002622-30-NL

Register	ID
CCMO	NL17735.018.07