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

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28986

Source
NTR

Brief title
PARIS

Health condition

Cervical cancer, endometrial cancer, pelvic radiotherapy, cystitis, quality of life, chondroitin sulphate

Cervix carcinoom, endometrium carcinoom, bekkenbestraling, cystitis, kwaliteit van leven, chondroitine sulfaat

Sponsors and support

Primary sponsor: Academic Medical Centre (AMC)
Source(s) of monetary or material Support: Academic Medical Centre (AMC)

Intervention

Outcome measures

Primary outcome

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

1. Voiding frequency in daytime and night time as assessed by a voiding diary;

2. Maximum bladder capacity as assessed by a voiding diary;

3. Pain domain, obstructive micturition domain, and incontinence domain of the UDI;

4. Generic quality of life as assessed by the SF36 Health Survey;

5. Cost-effectiveness;

6. Cost-utility (see economic evaluation);

7. Number of adverse events.

Study description

Background summary

Objective:

To evaluate whether preventive intravesical instillations with 0.2% chondroitin sulphate solution reduce bother related to acute radiation cystitis symptoms in patients undergoing pelvic radiotherapy for a gynaecologic malignancy. In addition we aim to define if it is cost-efficient to provide this intervention to patients undergoing pelvic radiotherapy for a gynaecologic malignancy.

Study design:

A double blind multicenter randomized controlled trial.

Study population:

Women, aged 18 years or older, who are indicated to undergo primary or adjuvant pelvic radiotherapy for a gynaecologic malignancy.

Intervention:

Participating patients will undergo weekly intravesical instillations with chondroitin sulphate solution or physiologic sodium chloride solution during the time of radiotherapy (mostly six weeks), starting between the 1st and 3rd day of radiotherapy. The intervention group will be instilled with 0.2% chondroitin sulphate solution and the control group with physiologic sodium chloride solution.

Outcome measures:

Primary objective is to evaluate whether intravesical instillations with 0.2% chondroitin sulphate solution reduce bother related to acute radiation cystitis symptoms patients undergoing pelvic radiotherapy. The main study parameter is the difference in Overactive Bladder domain score of the Urogenital Distress Inventory (UDI), measured 12 weeks after the patient received the first instillation.

Secondary objectives are to evaluate whether it is cost-efficient to provide intravesical instillations with 0.2% chondroitin sulphate solution to patients undergoing pelvic radiotherapy and to evaluate whether intravesical instillations with 0.2% chondroitin sulphate solution can reduce the prevalence of chronic radiation cystitis.

Power/data analysis:

Our pilot study showed that the median overactive bladder domain score of the patients who received the instillations at four weeks was 31 (SD 26) and of the controls 50 (SD 25). Revicki and colleagues state that the difference in domain score that can be considered to be clinically relevant is half of the SD in the intervention group. Based on these 2 sources we consider a difference of 13 points in the OAB domain score of the UDI to be clinically relevant. With a power of 80%, alpha level of 0.05 and standard deviation of 26, the calculated sample size necessary is 64 in each group. Accounting for 10% drop outs we will include 140 patients in total.

Economic evaluation:

The outcomes measures of the economic evaluation are, respectively, the costs per unit at the Urogenital Distress Inventory and the costs per quality adjusted life year (QALY). The time horizon is restricted to 6 months. With this short-time span, no discounting (of costs and effects) is performed. Incremental cost-effectiveness ratios are calculated, reflecting the extra costs per additional unit gained at the UDI and the extra costs per additional QALY. Sensitivity analyses will be performed to account for sampling variability (following bias corrected and accelerated non-parametric bootstrapping), for plausible ranges in unit costs

medical interventions, and for different health utility algorithms.

Study objective

Chondroitin sulphate can prevent complains of acute radiation cystitis in patients undergoing pelvic radiation therapy for gynaecologic malignancies.

Study design

1. Before first instillation/start radiotherapy (questionnaire + voiding diary);

2. During period of radiotherapy: once weekly voiding diary;

2. Four weeks after start radiotherapy (questionnaire);

3. Twelve weeks after start radiotherapy (questionnaire + voiding diary).

Intervention

Once weekly profylactic instillation with chondroitin sulphate solution or placebo (sodium chloride solution) during the period of pelvic radiotherapy.

Contacts

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Eligibility criteria

Inclusion criteria

1. Indicated to undergo primary or adjuvant pelvic radiotherapy for gynaecologic malignancy;

2. Aged 18 years or older;

3. Able to complete a Dutch questionnaire;

4. Written informed consent.

Exclusion criteria

1. Previous surgery of the lower urinary tract;

2. (Supra-pubic) catheter in situ;

3. Intermittent catheterisation because of bladder retention;

4. Intravesical treatment ≤ 6 months prior to inclusion;

5. Urinary tract infection (positive culture) ≤ 60 days prior to inclusion.

Study design

Design

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

Recruitment

NL
Recruitment status: Recruitment stopped

Start date (anticipated):	01-07-2011
Enrollment:	140
Type:	Actual

Ethics review

Positive opinion Date:	08-06-2011
Application type:	First submission

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
NTR-new	NL2787
NTR-old	NTR2927
Other	MEC AMC : 10/343
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A