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

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

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON28986

Bron
NTR

Verkorte titel
PARIS

Aandoening

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

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

Ondersteuning

Primaire sponsor: Academic Medical Centre (AMC)
Overige ondersteuning: Academic Medical Centre (AMC)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

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).

Onderzoeksproduct en/of interventie

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

Contactpersonen

Publiek

PO Box 22660

Jan-Paul W.R. Roovers
Department of Obstetrics and Gynaecology
Academic Medical Center (AMC)
Meibergdreef 9, H4-140-1
Amsterdam 1105 AZ
The Netherlands
+31 (0)20 5666429

Wetenschappelijk

PO Box 22660

Jan-Paul W.R. Roovers
Department of Obstetrics and Gynaecology
Academic Medical Center (AMC)
Meibergdreef 9, H4-140-1
Amsterdam 1105 AZ
The Netherlands
+31 (0)20 5666429

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-07-2011
Aantal proefpersonen:	140
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	08-06-2011
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL2787
NTR-old	NTR2927
Ander register	MEC AMC : 10/343
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A