Gag Therapy for Recurrent urine tract infection Assessing Comparability to International Nitrofurantoin Gold standard study.

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The main objective of the study is to compare efficacy between GAG therapy and gold standard treatment (AB prophylaxis) in the prevention of rUTI. Primary questionIs GAG therapy as efficacy as antibiotic prophylaxis in the prevention of rUTI?...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Urinary tract signs and symptoms
Study type	Interventional

Summary

ID

NL-OMON54106

Source
ToetsingOnline

Brief title
GT RACING

Condition

- Urinary tract signs and symptoms

Synonym
Urinary tract infections

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum

Source(s) of monetary or material Support: Goodlife Pharma BV,Goodlife Pharma BV en IBSA Pharmaeuticals,IBSA pharmaceuticals

Intervention

Keyword: Antibiotic, GAG therapy, Prevention, Urinary Tract Infections

Outcome measures

Primary outcome

The main study parameter is the number of UTI per patient per treatment.

Secondary outcome

Secondary parameters are

- Time to first recurrence of UTI

- Changes in the outcome on the GRA scale during follow-up.

- Differences in the pattern of antibiotic resistance between both treatments

(measured with urine cultures and antibiograms)

- Cost effectiveness of both therapies (measured with iMCQ and iPCQ)

- Changes in quality of life during both treatments (measured with ED-5D-5L)

- Changes in therapy specific patient reported outcomes during both treatments

(measured with Therapy specific patient reported outcome questionnaire)

- Side effects in both treatments, measured with Clavien-Dindo-system

Study description

Background summary

Antibiotic (AB) prophylaxis is the most common applied therapy for recurrent urinary tract infection (rUTI) in the Netherlands. However it contributes to antibiotic resistance, which is an increasing problem in healthcare. There is thus a large societal incentive to decrease AB use and apply alternative therapies. Previous studies (Damiano et al 2011, Goddard et al 2018) have shown

that GAG therapy (bladder instillations with GAG molecules) is valuable in the treatment of rUTI. However there is insufficient evidence comparing the effectiveness of GAG therapy with the effectiveness of antibiotic prophylaxis in the prevention of rUTI.

We hypothesize that GAG therapy is an effective alternative for antibiotic prophylaxis in the prevention of recurrent urinary tract infections. Furthermore we hypothesize that GAG therapy will lead to less antibiotic resistance than antibiotic prophylaxis.

Study objective

The main objective of the study is to compare efficacy between GAG therapy and gold standard treatment (AB prophylaxis) in the prevention of rUTI.

Primary question
Is GAG therapy as efficacy as antibiotic prophylaxis in the prevention of rUTI?

Secondairy questions
- Is there a difference in time to first recurrence of UTI between both treatments?
- Does GAG therapy lead to less antibiotic resistance than antibiotic prophylaxis?
- How do patients preceive their symptoms during both therapies?
- Is there a difference in cost-effectiveness between both therapies?
- Is there a difference in therapy specific patient reported outcomes between both treatments?
- Is there a difference in quality of life during both treatments?

Study design

Cross-over randomized controlled trial. Study is set-up as non-inferiority, parallel group trial, with a 1:1 randomization.

Intervention

Intervention:
Bladder instillations with 50ml of sterile Ialuril weekly for 6 weeks, followed by monthly maintenance therapy for 6 months. Every bladder instillation will take around 30 minutes. The bladder instillations can be inserted by a nurse in the hospital, at the general practitioners office or by the patient them self.

Control:
Antibiotic prophylaxis with oral nitrofurantoin 100mg daily (1dd100mg or 2dd50mg) for 6 months. In case of resistance/intolerance/allergy for nitrofurantoin alternatively trimethoprim 100mg daily will be given for 6

months.

There is a four week wash-out period between treatments. The order of the treatments is determined through randomisation

Study burden and risks

The burden
Intervention (GAG therapy): Weekly bladder instillations for 6 weeks, thereafter instillations will be given monthly for the total duration of 6 months.
Control group: 1 tablet of antibiotic profylaxis every day for the duration of 6 months
Both groups:
Appointments: 3 site visits and 5 telephonic visits. Questionnaires: prior to a (telephonic) visit 3-5 questionairs must be filled out (depending on the visit). A study diary needs to be filled out to report weekly protocol adherence. Urine samples are taken at site visits.

The risk
The intervention: bladder instillations with GAG therapy are inserted with a catheter. Risk: UTI, discomfort during catheterization.
The controle: antibiotic prophylaxis (nitrofurantoin or trimethoprim). Risk: side effects or allergic reaction (nausea, vomiting, itching, fungal infection)
Risks are negligible in both groups.

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

1) Adult female patients (>18 years) who had at least 3 symptomatic UTI*s in the previous year with no adequate curable therapeutic options (e.g. bladder stones)
2) All UTI*s must be confirmed with a urine sediment with positive nitrite or positive urine cultures.

Exclusion criteria

Male, < 18 yrs, pregnant, already on GAG therapy, Gentamycin bladder instillations in the previous 2 months, allergic to Nitrofurantoin and Trimethoprim, urologic conditions: fistula, stones, cancer, BPS-IC, catheter, STD or a urinary diversion. Performing self-catheterisation > 1/day, GFR < 30, Severe lung or kidney disfunction, not tolerate catherization

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial

Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	20-10-2022
Enrollment:	100
Type:	Actual

Medical products/devices used

Generic name:	Gag therapy (bladder instillations): ialuril® Prefill
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	09-08-2022
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	06-04-2023
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	31-08-2023
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	22-01-2024
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	18-06-2024

Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL76892.091.22