Winclove CLEAR for recurrent urinary tract infections in women

No registrations found.

Ethical review	Positive opinion
Status	Other
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25899

Source
Nationaal Trial Register

Brief title
PROTON

Health condition

(Recurrent) Urinary Tract Infections / (Recidiverende) Urineweginfecties
Cystitis / Cystitis
Quality of Life / Levenskwaliteit

Sponsors and support

Primary sponsor: This study is performed at the research facility of CR2O by Prof. Dr. Eric Claassen (Principal Investigator) and Drs. Joost Flach (Coordinating Investigator).

Source(s) of monetary or material Support: Winclove Probiotics B.V. is the financial sponsor of the study.

Intervention

Outcome measures

Primary outcome

1. The differences in QoL between treatment arms according to UTI-QoL-questionnaire data and SF-36 scores after the intervention period.

2. The difference in UTI incidence between treatment arms, as measured by the mean number of patient-reported UTI episodes during the intervention period.

3. The difference in UTI symptom severity between treatment arms, as measured by mean Symptom & Burden questionnaire scores during the intervention period.

Secondary outcome

4. The difference in UTI incidence between treatment arms, as confirmed by a microbiome analysis of urine samples during the intervention period (ratio of lactobacilli to common uropathogens).

5. The difference between treatment arms in UTI-related health-care expenditures during the intervention period, as determined by the Health Economics questionnaire at day 180.

6. The total number of subjects in the active treatment arm, and the difference on the number of subjects between treatment arms, where probiotic strains from the formulation are identified in urine samples at day 1, 60, 120 and 180 as determined by a primary species-specific 16S ribosomal RNA sequencing analysis and – if positive – a follow-up strain-specific real-time quantitative 16S ribosomal RNA gene polymerase chain reactions.

7. The difference in UTI duration between treatment arms, as determined by mean patient-reported UTI duration during the intervention period.

Additionally, the difference delta (Δ) from baseline will be compared between treatment arms for all previously mentioned outcome parameters.

Study description

Background summary

Urinary tract infections (UTIs) have an inimical influence on patient quality of life (QoL) and over a third of patients are likely to develop recurrent UTIs (rUTI) within the next twelve months. Women in particular, as they are substantially more susceptible to infection than men. Currently, few effective prevention (or treatment) options for UTI exist, other than prophylactic antibiotics. The adverse effects associated with repeated use of antimicrobial prophylaxis pose an additional burden on patient QoL (e.g. Antibiotic Associated Diarrhoea or vaginal candidiasis). Moreover, antibiotic effectiveness is diminishing due to increasing antimicrobial resistance. Such resistance makes UTIs increasingly difficult to treat. The current needs of rUTI patients are therefore unmet and require new nonantibiotic treatment/prevention options. A growing body of evidence suggest that probiotics may protect against urogenital infections, among which UTIs. A new multispecies probiotic formulation for the prevention of UTI (Winclove CLEAR) has therefore been developed recently. Winclove CLEAR is developed to support the host and prevent pathogens from migrating to the bladder. It is suggested that the probiotic strains of Winclove CLEAR may prevent UTIs through local competition with uropathogens and through the production of antibacterial agents. It is therefore hypothesized that the probiotic formulation may reduce the incidence- and symptom severity of UTIs and improve patient QoL.

Study objective

It is hypothesized that the multi-species probiotic formulation Winclove CLEAR may reduce the incidence- and symptom severity of urinary tract infections in women and thus improve patient quality of life

Study design

T0, Visit 1, Day 0.

- Informed Consent, Screening, Questionnaires, Urine Sample, Treatment Administration.

T1, Visit 2, Day 60.

- Questionnaires, Urine Sample.

T2, Visit 3, Day 120.

- Questionnaires, Urine Sample.

T3, Visit 4, Day 180.

- Questionnaires, Urine Sample, Treatment Seized. End of study.

Intervention

In this two-armed clinical trial, participants will be randomized (1:1) to either Winclove CLEAR or matching placebo.

- Active treatment: Participants (N = 20) consume a daily dose of 4g of Winclove CLEAR containing 4E+09 CFU of live probiotic strains L. pentosus W2 (KCA1), L. acidophilus W22, L. plantarum W21, L. salivarius W24, L. brevis W63, L. casei W56 and L. helveticus W74, cranberry extract (36 mg PACs) and D-mannose (1g) for a period of 6 consecutive months.

- Placebo: Participants (N = 20) consume a daily dose of 4g of the placebo formulation, similar in taste/smell/appearance but without active ingredients (e.g. probiotic, cranberry, D-mannose), for a period of 6 consecutive months.

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Eligibility criteria

Inclusion criteria

In order to be eligible for inclusion, a subject must meet all

of the following criteria:

1. rUTI* for at least 2 years (defined as 3 or more episodes of UTI per year).

2. At least 3 UTIs in the preceding 12 months.

3. Aged between 18 and 70 years.

4. Willing to take probiotics and refrain from UTI prophylaxis during the study.

5. Signed informed consent.

* (Recurrent) Urinary Tract Infections

Exclusion criteria

A potential subject who meets any of the following criteria will be

excluded from participation in this study:

1. Current (complicated) suspected UTI or cystitis

2. Prophylactic antibiotic usage during the intervention period

3. Probiotic, D-mannose or cranberry extract usage during the intervention period

4. Use of UTI prophylactics/treatments during the intervention period, other than mentioned under point 2 & 3, which in the opinion of the investigator may significantly interfere with the evaluation of the study objectives, including: estrogen treatment,

immunoprophylaxis, methenamine Hippurate, ascorbic acid supplementation, acupuncture, UTI specific vaccines and endovesical instillation (of hyaluronic acid and chondroitin sulphate)*.

5. Concurrently enrolled in another intervention study

(observational studies or inclusion following completion of another study is allowed (4-week wash-out))

6. Known to have interstitial cystitis or bladder pain syndrome

7. Known to have a complex bladder disturbance (e.g. cystoplasty, renal and bladder calculus, significant hydronephrosis or current pyelonephritis)

8. Known to have severe renal or hepatic failure

9. Known to be severely or terminally ill

10. Known to have non-resolvable urinary obstruction

11. Known to have a history of adverse drug reaction to yoghurt or milk products or a demonstrated intolerance to the probiotics used

- lactose intolerance is NOT an exclusion criterion

12. Known to be intolerant or allergic to any of the ingredients in both Winclove CLEAR and matched placebo

13. Spinal cord injury with suprapubic permanent catheter

14. Requiring full (invasive) mechanical ventilation

15. Receiving immunosuppressant medications or having an underlying immunosuppressive disease (e.g. HIV, end-stage / progressive diabetes mellitus, multiple sclerosis or cerebrovascular disease)

16. Planned oral/vaginal/urinary tract/bladder/gastrointestinal surgery during the intervention period

17. Recent oral/vaginal/urinary tract/bladder surgery/gastrointestinal (within last 3 months)

18. Pregnant females (screened with a positive pregnancy test), lactating or intending to become pregnant during the study. Women of childbearing potential need to use contraceptives

19. Use of intravaginal products (e.g. spermicides) except for menstrual products.

20. Any other condition, which, in the opinion of the investigator, may significantly interfere with the evaluation of the study

objectives

Study design

Design

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

Recruitment

NL

Recruitment status:	Other
Start date (anticipated):	21-01-2019
Enrollment:	40
Type:	Unknown

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	25-01-2018
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 46636
Bron: ToetsingOnline

Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL6832
NTR-old	NTR7069
CCMO	NL64708.072.18
OMON	NL-OMON46636

Study results

Summary results
The results of this study showed a significant improvement on the UTI-QoL questionnaire in the CLEAR group compared with control. No publication is available yet.