

Winclove CLEAR for recurrent urinary tract infections in women

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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

Ethische beoordeling	Positief advies
Status	Anders
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON25899

Bron

Nationaal Trial Register

Verkorte titel

PROTON

Aandoening

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

Ondersteuning

Primaire sponsor: This study is performed at the research facility of CR20 by Prof. Dr. Eric Claassen (Principal Investigator) and Drs. Joost Flach (Coordinating Investigator).

Overige ondersteuning: Winclove Probiotics B.V. is the financial sponsor of the study.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

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

Deelname

Nederland	
Status:	Anders

(Verwachte) startdatum: 21-01-2019
Aantal proefpersonen: 40
Type: Onbekend

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies
Datum: 25-01-2018
Soort: Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 46636
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten

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.