A pilot study on symptomatic treatment of uncomplicated urinary tract infections in general practice.

Published: 12-03-2010
Last updated: 02-05-2024

The objective of the proposed pilot study is to explore acceptability and feasibility of structured and adequate symptomatic treatment in adult women with uncomplicated UTI.

Ethical review	Approved WMO
Status	Will not start
Health condition type	Bacterial infectious disorders
Study type	Interventional

Summary

ID

NL-OMON34751

Source
ToetsingOnline

Brief title
Symptomatic treatment of uncomplicated urinary tract infections.

Condition

- Bacterial infectious disorders
- Urinary tract signs and symptoms

Synonym
bladder infection, urinary tract infection

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Acceptability, Symptomatic treatment, Uncomplicated urinary tract infection

Outcome measures

Primary outcome

The primary endpoint will be acceptability (percentage of women who agreed to participate in the study).

Secondary outcome

Secondary endpoints will be number of *failures* and dropouts, compliance with the treatment, duration of symptoms, recurrence rates of urinary tract symptoms, complications of UTIs (pyelonephtitis, sepsis), hospital admission, quality of life as measured using SF12 health survey and absence from work.

Study description

Background summary

Symptoms of urinary tract infections (UTIs) are among the most frequent clinical presentations in primary care with annual incidences ranging from 30 to 40 per 1000 patients [1]. Around 90% of those presenting are adult women. The most important pathogen in these female primary care patients is Escherichia coli (70 * 80%). Other pathogens like Proteus mirabilis, Klebsiella pneumoniae and Staphylococcus saprofiticus are present in about 20 to 30%. Bacterial resistance of these pathogens is a major problem in all EU countries. E.coli resistance to ampicillin ranges from 25% to 50%, to trimethoprim up to 25%, and to nitrofurantoin about 1 to 7% [2, 3,4,5]. Because of this rising problem of bacterial resistance it is important to restrict antibiotic use in UTIs as much as possible.
It has been suggested that uncomplicated UTIs are self-limiting [6] and symptomatic treatment may be effective in these patients. Also, it is known from current practice that a significant number of women with symptoms of a UTI wait a couple of days, before consulting their GP if the symptoms persist. In addition, many women follow a wait-and-see policy when they start having symptoms and experience that the symptoms usually disappear within few days.

Two placebo-controlled trials regarding urinary tract infections in primary care were found. They both showed that antibiotic treatment was significantly more effective than placebo in achieving bacteriological cure and symptomatic relief in patients with uncomplicated UTIs.[7,8] However, the control groups did not receive adequate systematic and symptomatic treatment. In the study by Christiaens et al., there was one clinical diagnosis of pyelonephritis in the placebo group after three days. The placebo group included 38 participants.[7] Ferry et al. also found that the risk of complications was low; two patients developed pyelonephritis, one receiving antibiotics for seven days and one receiving placebo. Their control group included 425 participants, the antibiotics group included 1143 subjects.[8] Thus it is still unknown whether antibiotic treatment of uncomplicated UTI has relevant advantages compared with symptomatic treatment. In addition, the frequent occurrence of side effects is a relevant problem in using antibiotics.
Subsequently the questions arises if symptoms of an uncomplicated UTI will diminish equally fast using adequate symptomatic treatment and drinking enough liquids, compared to using antibiotics. Therefore, we are currently preparing a randomised clinical trial comparing the effects of antibiotic treatment with symptomatic treatment in adult women with uncomplicated UTIs. Before conducting such a trial it is important to study acceptability and feasibility of structured and adequate symptomatic treatment in adult women with uncomplicated UTIs.

Study objective

The objective of the proposed pilot study is to explore acceptability and feasibility of structured and adequate symptomatic treatment in adult women with uncomplicated UTI.

Study design

The study is an pilot study. Participating GPs will ask women between 18 and 45 years old who present with an uncomplicated UTI to participate in this study. Following the 'NHG-standaard', the UTI will be confirmed using dipstick-testing and subsequently by dipslide (uricult) if nitrite is found to be negative.
After testing, urine samples will be destroyed according to standard procedures in the GP practices. Patients will be included after giving informed consent. Subjects will be advised to drink at least 2 litres of liquids per day and will be prescribed paracetamol 500 mg 2-3 times per day 2 tablets, or ibuprofen 400 mg 3 times a day during five days, after which they can the treatment if necessary.
They will receive a diary to record symptoms and possible adverse reactions for two weeks, this will take about 2 minutes a day. Also, they will be asked to fill out the SF-12 health survey after 7 and 14 days.
After a week they will be asked to deliver a second urine sample to their GPs practice. After two weeks they will be asked to send the diary to the

coordinating investigator. After these two weeks, follow-up is finished.
GPs will also be asked to record the number of eligible patients who decide not to participate, without registration of personal information.

Intervention

Women who agree to participate will be advised to drink at least 2 litres of liquids per day and will be prescribed paracetamol 500 mg 2-3 times per dag 2 tablets or ibuprofen 400 mg 3 times a day during five days, after which they can proceed the treatment if necessary.

Study burden and risks

The risk of complications of an uncomplicated UTI if not treated with antibiotics, can not be eliminated completely. In two recent trials by Christiaens et al. and Ferry et al., two cases of pyelonephritis were reported in the control groups (including 463 subjects in total).[7,8] Ferry et al. found one case of pyelonephritis in the antibiotic group (including 1143 subjects).[8]
Since the aforementioned placebo-controlled trials showed very few complications in the control group, we think the risk of not treating is acceptable. In addition, many women already follow a wait-and-see policy when they start having symptoms and experience that the symptoms usually disappear within few days.
The risk of pregnancy will not be eliminated by a pregnancy test, but it will be minimized by asking the subject what the chances of pregnancy are. If the subject can not be sure whether she is not pregnant, she will be excluded from participation.
The filling out and handing in of the diary and questionnaires, and the handing in of the urine sample will take about 80 minutes in total in 14 days.
A direct advantage to the subjects is the significantly reduced risk of side effects of paracetamol, compared to antibiotics (such as diarrhea, skin rash), because the normal bacterial flora is left intact.
A second advantage is less development of resistance to antibiotics in the society.
This study provides a relatively inexpensive and rapid insight into the acceptability of a symptomatic treatment of UTIs, and may provide the basis for a large randomized placebo-controlled trial.
Also, it serves the opportunity to obtain a better insight into the natural course of an uncomplicated UTI, with a small risk of complications.

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

- Women, 18-45 years of age
- Symptoms and diagnosis of UTI, according to the *NHG-standaard* (symptoms: painful or burning micturition (dysuria), frequency, urgency, hematuria, suprapubic pain).
- Who have provided written informed consent to participate

Exclusion criteria

Immunocompromised patients; pregnancy; diabetes mellitus; a known urological or nephrological disorder; fever, i.e. temperature above 38°C (axillary); pain in back and-or loin (kidney region); recurrent urinary tract infections (more than three occurrences per year during the past year or a UTI in the past three months); gynaecological complaints - such as abnormal vaginal discharge, labial irritation, intermittent vaginal bleeding; symptoms present for more than three days; taken antibiotics in the past four weeks.

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	100
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Paracetamol
Generic name:	paracetamol
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	12-03-2010
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	11-05-2010
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	22-06-2010
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

Approved WMO Date:	25-06-2010
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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
EudraCT	EUCTR2010-019078-33-NL
CCMO	NL31239.041.10