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Antibiotics versus ibuprofen for uncomplicated lower urinary tract infections: a randomised controlled double-blind clinical trial in German general practices

Submission date
10/08/2007

Recruitment status
No longer recruiting

Registration date
04/10/2007

Overall study status
Completed

Last Edited
25/02/2021

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English Summary
Background and study aims
Lower urinary tract infections (UTIs) are infections of the bladder or urethra (the tube that carries urine out of the body). They are usually treated with antibiotics. However, there is little evidence for alternative treatment options. The aim of this study is to find out whether the drug ibuprofen is as effective as the antibiotic ciprofloxacin for UTIs.

Who can participate?
Women aged 18 to 85 with at least one of the main UTI symptoms (painful/difficult or frequent urination)

What does the study involve?
Participants are randomly allocated to be treated with either ibuprofen or ciprofloxacin, both for three days. The intensity of their symptoms like painful/difficult or frequent urination and low abdominal pain are recorded at the start of the study and after 4, 7 and 28 days, scoring each symptom from 0 (none) to 4 (very strong).

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
29 German general practices

When is the study starting and how long is it expected to run for?
July 2007 to April 2008

Who is funding the study?
German Federal Ministry of Education and Research (Germany)

Who is the main contact?
Prof. Michael M. Kochen
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
HWI-01

Study information

Scientific Title
Antibiotics versus ibuprofen for uncomplicated lower urinary tract infections: a randomised controlled double-blind clinical trial in German general practices

Study hypothesis
1. The study demonstrates the feasibility of a randomised controlled double-blind clinical trial in German general practices
2. The results of the ibuprofen group allow the conduction of a larger trial in which the equivalence of ibuprofen and ciprofloxacin in Urinary Tract Infections (UTI) will be tested

Ethics approval required
Old ethics approval format

Ethics approval(s)
Local ethics committee (Ethikkommission der Universitaetsmedizin Goettingen), 13/06/2007, ref: 8/4/07

Study design
Randomised controlled double-blind clinical trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Condition
Uncomplicated lower urinary tract infection

Interventions
There are two intervention arms:
1. Ciprofloxacin 2 x 250 mg for three days (and one placebo per day)
2. Ibuprofen 3 x 400 mg for three days

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Ciprofloxacin, ibuprofen

Primary outcome measure
1. Symptom score on day 4 (symptom score for dysuria, frequency and pain is measured on days 0, 4 and 7 by questionnaire and interviews)
2. Feasibility: descriptive measure, this will be determined by describing the results of:
2.1. Recruitment of General Practitioners (GPs)
2.2. Recruitment of patients
2.3. Number of complete/incomplete data sets
The feasibility will be assessed after the patient recruitment is finished.

Secondary outcome measures
1. Improvement of symptoms at days 4 and 7
2. Adverse events
3. Number of relapses
The trial duration for each patient is 28 days. The adverse effects and relapses within these 28

days will be concerned. We plan to find out about this by an interview on day 28, and by data collection from GPs data at monitoring visits.

Overall study start date
25/07/2007

Overall study end date
15/04/2008

Eligibility

Participant inclusion criteria
Women with typical symptoms of uncomplicated lower urinary tract infection (dysuria, frequency, lower abdominal pain)

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
150

Total final enrolment
79

Participant exclusion criteria
1. Fever, low back pain
2. Urinary tract infection during the last two weeks
3. Current treatmant with antibiotics/Non-Steroidal Anti-Rheumatics (NSAR)
4. Pregnant/breastfeeding women
5. Diabetes
6. Renal diseases
7. Allergy/intolerance to ibuprofen/ciprofloxacin
8. Contraindications for trial medication
9. Severe co-morbidities

Recruitment start date
25/07/2007

Recruitment end date
15/04/2008

Locations

Countries of recruitment

Germany

Study participating centre
Georg-August University of Gottingen
Gottingen
Germany
37075

Sponsor information

Organisation
Georg-August University of Gottingen (Georg-August-Universitat Gottingen, Universitatsmedizin) (Germany)

Sponsor details
c/o Professor M. M. Kochen
Humboldtallee 38
Gottingen
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Sponsor type
Hospital/treatment centre

Website
http://www.uni-goettingen.de/en/sh/1.html

ROR
https://ror.org/01y9bpm73

Funder(s)

Funder type
Government

Funder Name
Bundesministerium für Bildung und Forschung

Alternative Name(s)
Federal Ministry of Education and Research, BMBF

Funding Body Type

Government organisation

Funding Body Subtype
National government

Location
Germany

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	01/04/2011		Yes	No
Results article	results	26/05/2010	25/02/2021	Yes	No