kofam

Koordinationsstelle Forschung am Menschen

BEISPIELSTUDIE

Symptomatic therapy for uncomplicated lower urinary tract infections in an ambulatory setting: a randomized, double-blind trial

KATEGORISIERUNG

Gattung
Forschungsprojekt mit lebenden Personen

Art

Unterart
Klinischer Versuch mit Arzneimitteln (einschliesslich Kombinationen nach Art. 2 Abs. 1 Bst. f und g MepV)

BACKGROUND

Most urinary tract infections are uncomplicated. The disease is benign and self-limited, and the primary goal of treatment is symptom relief rather than cure. The study was designed to determine if initial symptomatic treatment, followed by optional delayed antibiotic treatment, was non-inferior to immediate antibiotic treatment, followed by optional delayed antibiotic treatment, in resolving symptoms.

METHODS

Women 18-70 years old, who had acute uncomplicated urinary tract infections, were randomly allocated to receive symptomatic treatment (diclofenac [Olfen®] 75 mg twice daily, followed by optional, delayed antibiotic treatment with a single dose of 3 g fosfomycin, if the patient thought it was necessary) or to receive immediate antibiotic treatment (norfloxacin [Norfloxacin-Teva®] 400 mg twice daily, for three days, followed by optional, delayed antibiotic treatment with single dose of 3 g fosfomycin if the patient thought it was necessary). To ensure blinding, Olfen® and Norfloxacin-Teva® were encapsulated in a GMP-facility by a pharmacist. Patients kept a diary for 10 days, in which they described symptoms. The researchers followed up with a telephone interview on days 10 and 30. The primary outcome of the trial was the proportion of patients whose symptoms resolved on day 4.

CATEGORISER-FRAGEN

Fällt das Forschungsprojekt in den Geltungsbereich des Humanforschungsgesetzes?
Ja

BECAUSE
This project was based on a study protocol that defined the exact procedures to be used. The study includes a relatively large number of persons and is not based on individual cases; thus, it is a "method-driven search for generalizable knowledge", which is defined as research by HRA. Women ("persons") who suffer from acute uncomplicated lower urinary tract infection ("research concerning human diseases") are treated with either diclofenac (Olfen®) or norfloxacin (Norfloxacin-Teva®).

Handelt es sich bei dem Forschungsprojekt um ein Projekt mit lebenden Personen?
Ja

BECAUSE
This project included women between 18-70 years old ("persons"), who suffered from acute uncomplicated lower urinary tract infection.

Handelt es sich bei dem Forschungsprojekt um einen klinischen Versuch im Sinne der KlinV oder der KlinV-Mep?
Ja

BECAUSE
The investigator randomly assigned (“prospectively assigned”) women ("persons") who suffered from acute uncomplicated lower urinary tract infection to receive either diclofenac (Olfen®) or norfloxacin (Norfloxacin-Teva®) ["health-related intervention (therapeutic measure]"). The study compared the proportion of patients whose symptoms resolved on day 4 ("to investigate its effect on health").

Wird in der Studie ein Arzneimittel (einschliesslich Kombinationen nach Art. 2 Abs. 1 Bst. f und g Medizinprodukteverordnung (MepV) vom 1. Juli 2020) untersucht?
Ja

BECAUSE
Effects of diclofenac (Olfen®) and norfloxacin (Norfloxacin-Teva®); [“medicinal products”] are investigated in this study.

Ist das Arzneimittel in der Schweiz zugelassen?
Ja

BECAUSE
This randomized-controlled, double-blind trial investigated the effects of diclofenac (Olfen®) and norfloxacin (Norfloxacin-Teva®), which are "medicinal products"). Both are "authorised" for the Swiss market (approval number for Olfen®: 55164 (Swissmedic) and Norfloxacin-Teva®: 55602 (Swissmedic)).

Wird in der Studie ein Placebo verwendet oder wird der Originalzustand des verwendeten Arzneimittels oder seine Verpackung verändert?
Ja

BECAUSE
This randomized-controlled, double-blind trial investigated the effects of diclofenac (Olfen®) and norfloxacin (Norfloxacin-Teva®), which are "medicinal products"). Both are "authorised" for the Swiss market. Neither product was provided in the original state (authorised), but were encapsulated instead.

-