kofam

Koordinationsstelle Forschung am Menschen

CASE STUDY

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

CATEGORISING

Kind
Research project involving living people

Type
Clinical trial

Subtype
Clinical trial with medicinal products (including combinations according to Art. 2 Para. 1 Letters f and g MedDO)

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.

QUESTIONS OF THE CATEGORISER

Does the research project come under the scope of application of the Human Research Act?
Yes

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®).

Is the research project a project involving living persons?
Yes

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

Is the research project a clinical trial?
Yes

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").

Does the trial involve investigating medicinal products (including combinations according to Art. 2 Para. 1 Letters f and g Medical Device Ordinance (MedDO) from the July 1, 2020)?
Yes

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

Is the IMP authorised in Switzerland?
Yes

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)).

Is a placebo used in the trial, or is the original status of the medicinal product or its packaging as approved by Swissmedic modified?
Yes

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.
