A SINGLE-CENTER, SINGLE-DOSE, OPEN-LABEL, RANDOMIZED, 4-WAY CROSSOVER STUDY TO EVALUATE THE PHARMACOKINETIC PROFILE OF FLURBIPROFEN FOLLOWING ADMINISTRATION OF 2 FLURBIPROFEN TRANSDERMAL FORMULATIONS COMPARED TO FROBEN® 50 MG AND YAKUBAN TAPE® IN HEALTHY SUBJECTS

Published: 15-04-2013
Last updated: 23-04-2024

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON38802

Source
ToetsingOnline

Brief title
Flurbiprofen transdermal patch relative bioavailability study

Condition

- Other condition

Synonym
Inflammation

Health condition

ontstekingen

Research involving
Human

Sponsors and support

Primary sponsor: PRA International EDS
Source(s) of monetary or material Support: farmaceutische industrie

Intervention

Keyword: flurbiprofen, transdermal patch

Outcome measures

Primary outcome

Pharmacokinetics: plasma concentrations and PK parameters

Dermal evaluations, patch adhesion, amount of adhesive residue application

site, difficulty of patch removal, residual drug

analysis

Safety: AEs, vital signs, ECG, clinical laboratory assessments, physical

examination

Secondary outcome

n/a

Study description

Background summary

The flurbiprofen transdermal system (FTS) is a new, investigational, not registered as a drug, transdermal application form (transdermal means: patch for administration via the skin) of the known drug flurbiprofen that may eventually be used as an anti-inflammatory drug.
This is the first time that this particular formulation of flurbiprofen, FTS, will be tested in humans. In addition to two formulations of the FTS applied for 24 hours, you will receive a single dose of registered Froben®, a tablet that contains flurbiprofen and 2 Yakuban Tape® transdermal patches that also contain flurbiprofen and will be applied consecutively for 12 hours. These Yakuban Tape® transdermal patches are not registered in the European Union.

Study objective

The purpose of the study is to investigate how quickly and to what extent flurbiprofen is absorbed and eliminated from the body (this is called pharmacokinetics) when it is administered via a FTS. Furthermore, the pharmacokinetics of FTS will be compared to oral administration of Froben® and application of Yakuban Tape®. In addition, the safety and tolerability of FTS will be investigated.

Study design

The study will consist of 4 periods during which the volunteer will stay in de clinical research center in Zuidlaren for 5 days (4 nights) for each period. The time interval between leaving the clinical research center and entering the clinical research center for the next period will be at least 7 days. A follow-up phone call will take place 7-10 days after discharge from the clinic in Period 4.

For each period the volunteer is expected at the clinical research center at 14:00 h in the afternoon prior to the day of study medication administration.

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Intervention

On Day 1 of each period a 50 mg Froben® tablet will be administered with 240 ml of water in Period 1 after a fasting period (no food or drinks) of at least 10 hours. During 2 out of the 3 remaining periods a FTS will be applied on the lower back for 24 hours after a fasting period of at least 10 hours. During 1 of the 3 remaining periods two Yakuban Tape® patches will be applied on the

lower back each for 12 hours after a fasting period of at least 10 hours for the first patch. Study personel will press the patches firmly in place, using the palm of the hand for at least 30 seconds to assure good adhesion.
For Period 1 no fluids will be allowed from 1 hour before drug administration until 1 hour after drug administration. Thereafter, fluids are allowed freely.
For Periods 2, 3 and 4 fluids are allowed freely after patch application. In all periods fasting will continue for 4 hours until lunch is provided.

Study burden and risks

Procedures: pain, light bleeding, heamatoma, possibly an infection.

Other transdermal formulations that contain flurbiprofen have been administered in humans and were shown to be safe and tolerable. Some of the documented side effects with Yakuban Tape® include: itching, redness, rash, and tingling at the site of patch application.

This is the first time that this particular transdermal system of flurbiprofen, FTS, will be tested in humans. Though local tolerability was good in animal experiments, local skin irritation may be a side effect of FTS.

Flurbiprofen administered through a tablet has well-documented side effects of which the most important are: edema, abdominal pain, constipation, diarrhea, indigestion/heartburn, elevated liver enzymes, flatulence, gastrointestinal bleeding, nausea, vomiting, body weight changes, headache, nervousness, anxiety, insominia, increased reflexes, tremor, amnesia, fatigue, depression, malaise (feeling sick), somnolence, rhinitis, rash, changes in vision, dizziness, tendinitis and tinnitus.

With the doses used in this study, no serious adverse effects are expected. The occurrence of known or other (unknown) effects cannot be excluded. All potential drugs cause adverse events to some extent.

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

healthy male and female subjects
18-40 yrs, inclusive
BMI: 18.0-30.0 kg/m2, inclusive
non-smoking
light skin color

Exclusion criteria

Suffering from hepatitis B, hepatitis C, cancer or HIV/AIDS. In case of participation in another drug study within 90 days before the start of this study or being a blood donor within 60 days from the start of the study. In case of donating more than 1.5 liters of blood in the 10 months prior the start of this study.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover

Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	24-04-2013
Enrollment:	18
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Froben®
Generic name:	Froben®
Product type:	Medicine
Brand name:	Yakuban Tape®
Generic name:	Yakuban Tape®

Ethics review

Approved WMO

Date:	15-04-2013
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

Approved WMO

Date:	19-04-2013
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

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	EUCTR2013-001054-99-NL
CCMO	NL44397.056.13