A single-center, open-label, randomized, 3-way crossover study to evaluate the pharmacokinetic profile and tolerability of Flurbiprofen following administration of two Flurbiprofen transdermal formulations compared to Yakuban Tape® in healthy subjects

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

Summary

ID

NL-OMON40944

Source
ToetsingOnline

Brief title
Flurbiprofen transdermal patch pharmacokinetics study

Condition

- Other condition
- Joint disorders

Synonym

Inflammation

Health condition

ontstekingen, reumatoïde artritis, spieraandoeningen

Research involving
Human

Sponsors and support

Primary sponsor: Noven Pharmaceuticals, Inc.
Source(s) of monetary or material Support: Farmaceutische industrie

Intervention

Keyword: Flurbiprofen, transdermal patch

Outcome measures

Primary outcome

To evaluate the PK profile of flurbiprofen following the administration of two

different formulations of FTS (35 mg flurbiprofen / 70 cm2).

Secondary outcome

To compare the PK profile of flurbiprofen following a single 24-hour

application of FTS (35 mg flurbiprofen / 70 cm2) to that following a

twice-a-day application of Yakuban Tape® (20 mg flurbiprofen / 70 cm2).

To assess the adhesion, discomfort, irritation and adhesive residue of the

transdermal systems.

To assess the safety and tolerability of FTS and Yakuban Tape®.

Study description

Background summary

Flurbiprofen Transdermal System (FTS) is a new transdermal formulation (a patch

for administration via the skin) of the registered anti-inflammatory drug flurbiprofen. FTS is being developed and is not registered as a drug but has been given to humans before in a similar formulation. Flurbiprofen is not a new drug; it is already available in the market under several dosages and formulations. In addition to the two formulations of the FTS applied for 24 hours, you will receive 2 Yakuban Tape® transdermal patches that also contain flurbiprofen and will be applied twice for 12 hours (24 hours in total). These Yakuban Tape® transdermal patches are not registered in the European Union but are registered in Asia.

Study objective

The purpose of the study is to investigate to what extent the FTS patches are tolerated. It will also be investigated how quickly and to what extent flurbiprofen from the FTS patch is absorbed and eliminated from the body (this is called pharmacokinetics).

Study design

The actual study will consist of 3 periods during which the volunteer will stay in the clinical research center in Zuidlaren for 5 days (4 nights). The time interval between the different periods is between 6 and 8 days.
For each period, the volunteer is expected at the clinical research center at 14:00 h in the afternoon prior to the day of (first) administration of study medication. The volunteer will leave the clinical research center on Day 4 (Day 1 is the day of administration of study medication). Between 7 and 10 days after you have left the clinic after Period 3 the volunteer will be called for a short follow-up.

Intervention

During the study, the flurbiprofen patches will be applied to the lower back for 24 hours (FTS-A2 and FTS-B2) or 2 times 12 hours (Yakuban Tape®). Study personnel will apply the patches and will press the patches firmly in place, using the palm of the hand for at least 30 seconds to assure good adhesion. From 10 hours before until 4 hours after the application of the (first) patch the volunteer is not allowed to eat or drink anything except for water. The volunteer will receive a lunch 4 hours after application of the study medication in each period.

Study burden and risks

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 these particular transdermal systems 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. An earlier version of the FTS patches did not have unexpected adverse effects. Flurbiprofen administered through a tablet has well-documented side effects of which the most important are: edema (swelling caused by fluid retention), abdominal pain, constipation, diarrhea, indigestion/heartburn, elevated liver enzymes, flatulence, gastrointestinal bleeding, nausea, vomiting, body weight changes, headache, nervousness, anxiety, insomnia, increased reflexes, tremor, amnesia, fatigue, depression, malaise (feeling sick), somnolence, rhinitis, rash, changes in vision, dizziness, tendinitis and tinnitus.

Procedures: pain, minor bleeding, bruising, possible infection

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 subjects
18-65 years, inclusive
BMI: 18.0-30.0 kg/m2, inclusive

Exclusion criteria

Suffering from hepatitis B, hepatitis C, cancer or HIV/AIDS. In case of participation in another drug study within 60 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):	08-05-2014
Enrollment:	18
Type:	Actual

Medical products/devices used

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

Ethics review

Approved WMO Date:	07-04-2014
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	22-04-2014
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	EUCTR2014-001016-19-NL
CCMO	NL48836.056.14