A single-center, randomized, open-label, 3 way crossover study to evaluate the single and multiple dose pharmacokinetic profile of HP-5000 compared to PENNSAID® 2% in healthy volunteers

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To investigate how quickly and to what extent diclofenac is absorbed and eliminated from the body (this is called pharmacokinetics) when it is administrated by using a HP 5000 transdermal patch. Furthermore, the pharmacokinetics of HP-5000...

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

Summary

ID

NL-OMON42086

Source
ToetsingOnline

Brief title
HP-5000 / PENNSAID 2% 3 way crossover study

Condition

- Other condition

Synonym
Inflammation

Health condition

onstekingen

Research involving
Human

Sponsors and support

Primary sponsor: PRA Health Sciences
Source(s) of monetary or material Support: Farmaceutische industrie

Intervention

Keyword: Diclofenac, HP-5000, Transdermal patch

Outcome measures

Primary outcome

The primary objective is to evaluate the single and multiple dose PK of

Diclofenac and dimethyl sulfoxide (DMSO), obtained from two formulations of

HP-5000 compared to PENNSAID® 2%

Secondary outcome

* To evaluate irritation, adhesion, discomfort, pain and adhesive residue of

two formulations of HP-5000

* To evaluate the safety and tolerability of two formulations of HP-5000

Study description

Background summary

The drug to be given is an existing compound, diclofenac, in a new application form, transdermal patches (transdermal means: patch for administration via the skin). Diclofenac is an anti inflammatory drug and is available in the market under several dosages and formulations.

In this study a new administration method of diclofenac, the HP-5000 transdermal patch, will be tested. This form of diclofenac-containing transdermal patches is not registered but similar formulations with a lower dose of diclofenac have been given to humans before.

In addition to diclofenac in the new application form (transdermal patches), the volunteer will receive PENNSAID® 2%. This is a diclofenac-containing solution that will be applied to the skin. This is a registered medication.

Study objective

To investigate how quickly and to what extent diclofenac is absorbed and eliminated from the body (this is called pharmacokinetics) when it is administrated by using a HP 5000 transdermal patch. Furthermore, the pharmacokinetics of HP-5000 transdermal patches will be compared to the pharmacokinetics of PENNSAID® 2% diclofenac solution. In addition, the safety and tolerability of the HP-5000 transdermal patch will be investigated.

Study design

The actual study will consist of 3 periods during which the volunteer will stay in the clinical research center in Zuidlaren for 18 days (17 nights) in each period. The time interval between the different periods is at least 16 full days (between the last blood sample in one period and the first medication administration in the next period).

During the study, in each period HP 5000 75, HP 5000 DRS400, or PENNSAID® 2% solution will be applied to the skin in the morning of Day 1, and the mornings of Day 3 up to and including Day 16. Thereafter you will receive breakfast. The administration of PENNSAID® 2% solution will be repeated after 12 hours on Days 3 through 16.

Intervention

During this study the volunteer will receive in random order 3 treatments in 3 periods. The volunteer will thus receive each treatment once and will receive only 1 treatment in each period. The order in which the volunteer will receive these treatments will be determined by chance.

Treatment A: HP-5000-75* transdermal patches, containing 150 mg diclofenac sodium per 140 cm2;
on Day 1 and from Day 3 up to and including Day 16 once daily (every 24 hours) a new patch will be applied to the upper part of the back.
Treatment B: HP-5000-DRS400 transdermal patches, containing 150 mg diclofenac sodium per 140 cm2;
on Day 1 and from Day 3 up to and including Day 16 once daily (every 24 hours) a new patch will be applied to the upper part of the back.
Treatment C: PENNSAID® 2% solution, containing 40 mg diclofenac sodium per 2 mL; once on Day 1 and twice daily from Day 3 up to and including Day 16, 2 mL will be applied to an area of 140 cm2 on the upper part of the back

In every period, Day 1 is the day of first study medication application.

Study burden and risks

The HP-5000 transdermal patches were tested in earlier studies. The most frequently reported adverse events were application site reactions, such as itch (pruritus). As with other transdermal system products, the use of the patches may occasionally lead to symptoms of contact dermatitis (this is a skin reaction or eczema caused by contact with irritating substances or substances that a person is allergic to) such as redness, rash, eruption, flare, itching, pigmentation, skin irritation and loss of hair at the site of application. The active ingredient, diclofenac, also has known adverse effects as described below.

PENNSAID® 2% solution for application on the skin is a registered drug containing diclofenac as active ingredient. It is available in the United States since February 2014. Since 2009, PENNSAID® 1.5% solution has been registered as a drug and is used in the United States. The most frequently reported adverse events after application of diclofenac in the form of PENNSAID® 1.5% are skin reactions at the application site, such as dryness, redness, and contact dermatitis (skin reaction/eczema) with redness and hardening of the skin or with blisters and itching. Other frequently reported adverse effects of PENNSAID® are stomach upset (dyspepsia: symptoms are upper abdominal pain or fullness, burping, nausea, vomiting and heartburn), stomach pain, gas, diarrhea and nausea. The reported adverse effects after application of PENNSAID® 2% solution are comparable to those reported for PENNSAID® 1.5%.

Other frequently reported adverse effects of diclofenac in general include headache, dizziness, vertigo, anorexia (lack of appetite), and rashes.

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 volunteers
18 - 65 years, inclusive
18 - 30 kg/m2, inclusive

Exclusion criteria

Suffering from hepatitis B, hepatitis C, cancer or HIV/AIDS. In case of participation in another drug study within 30 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):	03-11-2014
Enrollment:	18
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Diclofenac sodium
Generic name:	n.v.t.

Ethics review

Approved WMO Date:	20-10-2014
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	31-10-2014
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	EUCTR2014-002456-61-NL
CCMO	NL51107.056.14