A pharmacokinetic study to compare the bioavailability between MK-0663 (etoricoxib) 120 mg Tablets from Two Different Manufacturing Sites (Frosst Iberica, Spain versus Elkton, VA, USA).

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The primary objective(s) of this study is:- To determine the relative bioavailability of etoricoxib 120 mg tablets manufactured at Frosst Iberica, Spain and Elkton, VA, USA.

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

Summary

ID

NL-OMON37397

Source
ToetsingOnline

Brief title
MK-0663 (CS0177)

Condition

- Joint disorders

Synonym
arthrosis, rheumatism

Research involving
Human

Sponsors and support

Primary sponsor: Merck Sharp & Dohme (MSD)
Source(s) of monetary or material Support: MSD

Intervention

Keyword: bioavailability, etoricoxib, pharmacokinetics

Outcome measures

Primary outcome

To determine the relative bioavailability of etoricoxib 120 mg tablets

manufactured at Frosst Iberica, Spain and Elkton, VA, USA.

Secondary outcome

To evaluate the safety and tolerability of a single dose of 120 mg etoricoxib

manufactured at Frosst Iberica, Spain and Elkton, VA, USA, in healthy adults.

Study description

Background summary

Etoricoxib tablets are currently manufactured at Elkton, VA, USA, but a site transfer will take place to Frosst Iberica, Spain. The regulatory authorities of Taiwan require a bioequivalence assessment to support such changes. Hence, the current study is being conducted to establish bioequivalence between etoricoxib 120 mg tablets manufactured at Frosst Iberica, Spain and Elkton, VA, USA.

Study objective

The primary objective(s) of this study is:
- To determine the relative bioavailability of etoricoxib 120 mg tablets manufactured at Frosst Iberica, Spain and Elkton, VA, USA.

Study design

This is an open-label, randomized 2-period crossover study to assess the in vivo pharmacokinetics of 120 mg etoricoxib tablets manufactured at Frosst

Iberica, Spain and Elkton, VA, USA, conducted at one site with healthy volunteers.

Intervention

The study will start with a screening. A few standard medical assessments will be performed (physical examination, ECG, vital signs). Furthermore a blood and urine sample will be taken for laboratory tests and an alcohol breath test and drug screen will be done.
During the stay in the clinic (two times) the subject will receive the study medication and on several time points blood will be taken. The subjects will be asked for possible side effects on regular basis. Furthermore safety assessments will be done frequently.
During the ambulant visits (8 times) blood will be taken and the subjects will be asked for possible side effects.

Study burden and risks

Etoricoxib is a registered drug that is well tolerated. However, as with any medicine, it is possible that etoricoxib can cause side-effects.

In several clinical studies in which patients with osteoarthritis, rheumatoid arthritis, chronic low back pain and acute pain received one daily dose of Etoricoxib for 1 to 12 days, the following side effects occurred: asthenia/fatique, dizziness, swelling of the legs and/or feet due to oedema, hypertension, heartburn, nausea, headache and changes in the results of a bloodtest for the liver.
The dose level that is used in this study is the highest dose level that is prescribed to patients. The risk to the above mentioned side effects is limited since the dose level is administered as a single dose in each treatment period, but the subjects may experience one of the above mentioned side-effects or other symptoms not previously reported. The health of the subjects will be closely monitored during the trial to minimize these risks.

The blood collection procedure may cause discomfort or bruising. Occasionally, fainting or an infection at the blood sampling site can occur.

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

Male and female, between 18-55 years of age, BMI 18-30.

Exclusion criteria

Clinical significant abnormalities at medical research

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Masking:	Open (masking not used)
Control:	Uncontrolled

Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	23-02-2012
Enrollment:	24
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	etoricoxib
Generic name:	arcoxia
Registration:	Yes - NL intended use

Ethics review

Approved WMO

Date:	16-02-2012
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

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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	EUCTR2012-000549-11-NL
CCMO	NL39810.056.12