An Open-Label, Single-Dose Study to Evaluate the Pharmacokinetics of CG5503 Immediate-Release Capsule in Healthy Elderly and Young Subjects

Published: 23-08-2006
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nvt

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

Summary

ID

NL-OMON30712

Source
ToetsingOnline

Brief title
CG5503 IR pharmocokinetics in young and elderly

Condition

- Other condition

Synonym
chronic pain, pain

Health condition

acute en chronische pijn

Research involving
Human

Sponsors and support

Primary sponsor: Johnson & Johnson Pharmaceutical
Source(s) of monetary or material Support: Johnson and Johnson Pharmaceutical Research and Development LLC;in the Netherlands represented by Janssen-Cilag B.V.;Dr. Paul Janssenweg 150;5026 RH Tilburg.

Intervention

Keyword: CG5503, pain, pharmacokinetics

Outcome measures

Primary outcome

nvt

Secondary outcome

nvt

Study description

Background summary

nvt

Study objective

nvt

Study design

nvt

Intervention

nvt

Study burden and risks

nvt

Contacts

Public
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Scientific
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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
female (surgically sterilized or post-menopausal for at least two years or use for this study an acceptable method of birth control)
age 18-45 years
age 65 years and older
BMI is between 20 - 30 kg/m2 with a weight of not less than 50 kg
no smoking or you not smoking more than 10 cigarettes/day
Kidney function: for elderly CLCR > 60 mL/min; for young subjects CLCR at least 80 mL/min

Exclusion criteria

Important medical disorder, e.g., hepatitis B, cancer or HIV/AIDS.
Participation in another drug study within 60 days before the start of this study.
Blood donation within the 90 days prior to the start of this study or sudden blood loss of similar amount of blood.

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	20-09-2006
Enrollment:	32
Type:	Actual

Ethics review

Approved WMO

Date:	23-08-2006
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

Approved WMO

Date:	04-09-2006
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

Approved WMO

Date:	05-01-2007
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	17-01-2007
Application type:	Amendment
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	EUCTR2006-003982-15-NL
CCMO	NL13752.056.06