A single-center, open-label study to investigate the absorption, distribution, metabolism and excretion (ADME) of INC280 after a single oral dose of 600 mg [14C] INC280 (5.55 MBq) in healthy male subjects

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

Summary

ID

NL-OMON41012

Source
ToetsingOnline

Brief title
Human metabolism and mass balance study of INC280

Condition

- Other condition

Synonym
cancer

Health condition

verschillende vormen van kanker

Research involving
Human

Sponsors and support

Primary sponsor: Novartis
Source(s) of monetary or material Support: Farmaceutische industrie

Intervention

Keyword: 14C, cancer, INC280

Outcome measures

Primary outcome

* To determine the rates and routes of excretion of [14C]INC280 related

radioactivity, including mass balance of total drug-related radioactivity in

urine and feces, following the administration of a single 600

mg oral dose of [14C]INC280 to healthy male subjects.

* To determine the pharmacokinetics of total radioactivity in blood and plasma.

* To characterize the plasma pharmacokinetics of INC280

Secondary outcome

* To assess the safety and tolerability of a single 600 mg oral dose of

[14C]INC280 administered to healthy male subjects.

Study description

Background summary

INC280 is a new investigational compound that may eventually be used for the treatment of several forms of cancer. INC280 is a specific inhibitor of a protein (the c-MET receptor tyrosine kinase) which plays an important role in the development and progression of cancer. INC280 is not registered as a drug

but has been given to humans before.

Study objective

The purpose of the study is to investigate how quickly and to what extent INC280 is absorbed, distributed, metabolized (broken down) and eliminated from the body (this is called pharmacokinetics). The compound to be administered will be labeled with 14-Carbon (14C) and is thus radioactive (also called radiolabeled).

Study design

The actual study will consist of 1 period during which the volunteer will stay in the clinical research center in Zuidlaren for a minimum of 9 days (8 nights) or 15 days (14 nights).

During the study the volunteer will receive the study medication after an overnight fast (at least 10 hours) as 12 capsules of 50 mg each, together with a minimum of 240 milliliters and a maximum of 480 milliliters of water.

Fasting will continue until 4 hours after administration of the study medication. During fasting and after intake of the study medication, the volunteers are allowed to drink water as they wish with the exception of 2 hours prior to until 2 hours after administration of study medication.

One of the investigators will inspect the volunteers hands and mouth after study medication intake.

Intervention

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Study burden and risks

All potential drugs cause adverse events; the extent to which this occurs differs.

INC280 is an investigational drug and not all of the side effects are known. In previous clinical studies in healthy male subjects, a single dose of 600 mg INC280 was found to be safe and well-tolerated resulting in only mild side effects, which were primarily headache and nausea. Any possible long-term effects of INC280 are also unknown.

We do not know the side effects of INC280 when given in combination with other

drugs. A combination of drugs might result in serious side effects. Some over the-counter and prescription medications can reduce the effectiveness or increase the side effects of INC280. Likewise, INC280 can increase the side effects or lessen the effectiveness of some medications. This might result in serious or even life-threatening side effects. You should always discuss the use of any drugs (over- the-counter drugs, prescription, or illegal drugs or health food supplements) with your doctor before taking INC280 and while you are participating in this study.

In this study 14C-radiolabeled INC280 will be used. The amount of radioactivity in this dose will be approximately 5.55 MBq (MBq = megaBecquerel, this is a unit to express the amount of radioactivity in the study medication). The average environmental background radiation burden in The Netherlands is approximately 2 mSv per year (mSv = miliSievert, this is the unit which indicates the burden on the human body; thus the effect on the human body of the amount of radioactivity administered). The additional radiation burden in this study due to the administration of approximately 5.55 MBq 14C labeled INC280 is calculated to be 2.37 mSv. This is approximately 1.2 times the average annual radiation burden.

Procedures: pain, minor bleeding, bruising, possible infection.

Contacts

Public
Novartis

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CH
Scientific
Novartis

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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 subjects
45-65 years, inclusive
BMI: 18 - 29 kg/m2, inclusive

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 0.4 liters of blood in the 8 weeksprior the start of this study.

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):	12-11-2014
Enrollment:	6
Type:	Actual

Ethics review

Approved WMO Date:	07-10-2014
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	13-10-2014
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	EUCTR2014-002646-53-NL
CCMO	NL50854.056.14