A Phase I open-label study to investigate the mass balance and biotransformation of a single oral 160 mg (100 µCi) dose of 14C-MDV3100 (ASP9785) in healthy male subjects

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Primary objective:- To evaluate the pharmacokinetics, metabolism, and excretion of MDV3100 in plasma, urine, and feces after a single oral 160 mg (100 µCi) dose of 14C-MDV3100.Secondary objective:- To evaluate safety and tolerability of a single...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Reproductive neoplasms male malignant and unspecified
Study type	Interventional

Summary

ID

NL-OMON35823

Source
ToetsingOnline

Brief title
[14C]- MDV3100 tracer label study

Condition

- Reproductive neoplasms male malignant and unspecified

Synonym
prostate cancer, prostate carcinoom

Research involving
Human

Sponsors and support

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

Intervention

Keyword: 14C-MDV3100 (ASP9785), prostate cancer, radiolabeled

Outcome measures

Primary outcome

- radiokinetics

- pharmacokinetics

- safety

- tolerability

Secondary outcome

n/a

Study description

Background summary

MDV3100 is a new investigational compound that may eventually be used for the treatment of prostate cancer. MDV3100 is not registered as a drug but has been given to humans before.

Study objective

Primary objective:
- To evaluate the pharmacokinetics, metabolism, and excretion of MDV3100 in plasma, urine, and feces after a single oral 160 mg (100 µCi) dose of 14C-MDV3100.

Secondary objective:
- To evaluate safety and tolerability of a single oral 160 mg (100 µCi) dose of 14C-MDV3100.

Study design

Design:
This will be an open-label ADME study in 6 healthy male subjects receiving a single-dose study of 14C labeled studymedication (3,7 MBq; 0,99 mSv).

Procedures and assessments:
screening and follow up:
Screening consists of bestaat uit een medical history, physical exam, blood - urine analysis, (i.e. . alcohol, drugs, HBsAG, anti-HIV, anti-HCV), vital sigs, and an ECG. At entry a abbrevaiated physical exam will be performed, ECG and blood - urine analysis, (i.e. . alcohol, drugs, HBsAG, anti-HIV, anti-HCV),

observation period:
1 period in the clinic -17 h -240 h post dose , followed by minimal 5 short periods (Day 13-15, 20-22, 27-29, 34-36 and 48-50) of 3 days each (2 nights), with possible extention till Day 78 if the criteria have not been met (total extretion radioactivity *90%) on Day 50. If the release criteria have not been met on Day 50, the volunteer will be asked o come to the clinci for 2 additional periods (day 62-64 and 76-78).

Bloodsampling:
-Blood sampling for determination of plasma concentrations of MDV3100 and its metabolites MDPC0001 and MDPC0002 and of 14C radioactivity in plasma and whole blood will take place at pre dose and at 30min, 1h, 1h 30min, 2h, 3h, 4h, 6h, 8h, and 12h (Day 1), 24h (Day 2), 48h (Day 3), 72h (Day 4), 96h (Day 5), 168h (Day 8), 240h (Day 11), 312h (Day 14), 480h (Day 21), 648h (Day 28), 816h (Day 35) and 1152h (Day 49) post-dose.
-Blood sampling for metabolic profiling will take place at pre dose and at 2h, 6h and 12h (Day 1), 24h (Day 2), 48h (Day 3), 96h (Day 5), 168h (Day 8), 240h (Day 11), 312h (Day 14), 480h (Day 21), 648h (Day 28), 816h (Day 35) and 1152h (Day 49) post-dose.
- genotyping 1x on Day 1 (only period 1), post dose.
-Hematocrit will be measured at pre-dose and at 24h (Day 2), 48h (Day 3), 72h (Day 4), 96h (Day 5), 168h (Day 8) and 240h (Day 11) post-dose. No separate sample should be taken for hematocrit measurement: 1 mL of the blood sample for total radioactivity will be used.

Urine sampling:
- Urine sampling for determination of concentrations of MDV3100 and its metabolites MDPC0001 and MDPC0002 and of 14C radioactivity will take place at pre dose and collection intervals at 0-12, 12-24, 24-48, 48-72, 72-96, 96-120, 120-144, 144-168, 168-192, 192-216 and 216-240 hours post-dose and for 24 hours on Day 14 (312 336 hours), Day 21 (480-504 hours), Day 28 (648-672 hours), Day 35 (816-840 hours) and Day 49 (1152-1176 hours) post-dose.
- urine, sampling for metabolic profiling will take place at pre dose and at

2h, 6h and 12h (Day 1), 24h (Day 2), 48h (Day 3), 96h (Day 5), 168h (Day 8), 240h (Day 11), 312h (Day 14), 480h (Day 21), 648h (Day 28), 816h (Day 35) and 1152h (Day 49) post-dose.

Feces sampling:
-Feces sampling for determination of 14C radioactivity will take place at pre dose and in intervals at 0-24, 24-48, 48-72, 72-96, 96-120, 120-144, 144-168, 168-192, 192-216 and 216-240 hours post-dose and for 24 hours on Day 14 (312-336 hours), Day 21 (480-504 hours), Day 28 (648-672 hours), Day 35 (816-840 hours) and Day 49 (1152 1176 hours) post-dose.- feces sampling for metabolic profiling will take place at pre dose and at 2h, 6h and 12h (Day 1), 24h (Day 2), 48h (Day 3), 96h (Day 5), 168h (Day 8), 240h (Day 11), 312h (Day 14), 480h (Day 21), 648h (Day 28), 816h (Day 35) and 1152h (Day 49) post-dose.
Veiligheidsmaatregelen:
Bijwerkingen tijdens de hele studie. Klinisch chemisch lab op dag 11 en 35, ECG en vitale functies vóór dosering en 1 maal daags op dagen 2-10, 13-15, 20-22, 27-19, 34-36, 48-50 na dosering.

Bioanalysis:
-Analyse of the studymedication in plasma, urine and feces using validated methods by PRA,
-analysis of total radioactivity in whole blood, plasma, urine and faeces using validated methods by PRA
-metabolite and genotyping profile using validated methods by PRA

Intervention

active substance MDV3100 and [14C]- MDV3100

Study burden and risks

Procedures: pain, licht bleeding, bruses, possible infection.

In an earlier study with 60 healthy volunteers receiving a single dose of 160 mg given twice (one in fed and one in fasted condition) the most important adverse events reported were: headache, diarrhea, pharyngitis and skin laceration. All events were of mild intensity and resolved prior to the end of the study (clinical conduct part). The occurrence of known or other effects cannot be excluded. All potential drugs cause adverse events to some extent. Therefore you should take into account that some risks are still unknown at this moment.

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 male subjects
-18 to 55 years inclusive.
-BMI 18.5 to 30.0 kg/m2
-Non-smoker, or not more than 10 cigarettes for at least three months before drug administration

Exclusion criteria

Suffering from: hepatitis B, 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 90 days from the start of the study. In case of donating more than 1.5 liters of blood in the 12 months prior the start of this study. Participation is also not permitted when participated in more than 3 other drug studies in the 10 months prior to 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):	12-04-2011
Enrollment:	6
Type:	Actual

Ethics review

Approved WMO

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	EUCTR2011-000089-37-NL
CCMO	NL36015.056.11