ISRCTN89596264 https://doi.org/10.1186/ISRCTN89596264

Study of the rate of absorption of donepezil 10mg in the form of an orodispersible film versus donepezil 10mg in the form of an orodispersible tablet in healthy subjects under fasting conditions

Submission date	Recruitment status	[ ] Prospectively registered
07/02/2012	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
14/03/2012	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
25/09/2026	Mental and Behavioural Disorders	[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Donepezil is a medication that is used to treat for the symptoms of mild to moderately severe Alzheimer's dementia. It can be given as an orodispersible (mouth-dissolving) tablet or film. The aim of this study is to compare the rate and extent of absorption of Donepezil given as an orodispersible film or tablet to healthy volunteers.

Who can participate?
Healthy volunteers (non-smokers) aged between 18 and 55

What does the study involve?
For safety reasons a pregnancy test, an alcohol breath test and a urine drug/smoking test are carried out before dosing. Participants are randomly allocated to take Donepezil as either an orodispersible film or tablet. A total of 18 blood samples are collected during the following 72 hours. Blood pressure and heart rate are also measured before and after dosing. One month later the participants switch to take the other form of Donepezil and the measurements are repeated.

What are the possible benefits and risks of participating?
No benefits to the participants are expected. The risks are the same as those documented in the Donepezil product leaflet.

Where is the study run from?
Alkemira SA, Switzerland.

When is study starting and how long is it expected to run for?
February to March 2012

Who is funding the study?
Alkemira SA, Switzerland.

Who is the main contact?
Giorgio Reiner, giorgio.reiner@alkemira.com

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
110559

Study information

Scientific Title
Randomised, open-label, 2-way crossover bioequivalence study of donepezil 10mg orodispersible film versus donepezil 10mg orodispersible tablet in healthy subjects under fasting conditions

Study objectives
Compare the rate and extent of absorption of donepezil 10 mg orodispersible film (test) versus Aricept Evess orodispersible tablet (control), administered without water under fasting conditions.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Institutional Review Board/CTA approval ref: 9427-A2419-21C

Primary study design
Interventional

Study design

Single centre open-label randomised single-dose crossover study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Alzheimer's disease

Interventions
Donepezil Renantos 10 mg orodispersible film, only one administration per subject without water under fasting conditions. Blood collections will be during the 72 hours after administration.

Aricept Evess 10 mg orodispersible tablets, only one administration per subject without water under fasting conditions. Blood collections will be during the 72 hours after administration.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Donepezil

Primary outcome(s)
In each period, a total of 18 blood samples will be drawn from each subject for pharmacokinetic analyses. Blood samples will be collected prior to drug administration and 0.5, 1, 1.5, 2, 2.5, 3, 3.5, 4, 4.5, 5, 6, 8, 12, 24, 36, 48, and 72 hours post-dose (3 mL for each sampling time).

Blood pressure and heart rate will also be measured prior to dosing and approximately 2, 4, 8, and 24 hours post-dose. Oral temperature will be measured at screening and at study exit.

A urine drug screen (amphetamines, methamphetamines, barbiturates, benzodiazepines, tetrahydrocannabinol, cocaine, opiates, phencyclidine, MDMA, methadone) and a urine cotinine test will be performed at screening. A urine drug screen, a urine cotinine test, and an alcohol breath test will be performed before dosing of each period

Key secondary outcome(s)
1. Blood pregnancy
2. Test demographic datamedical and medication histories
3. Physical examination
4. Body measurements
5. Electrocardiogram (12-lead ECG)
6. Vital signs (blood pressure, heart rate, and respiratory rate)
7. Oral temperature
8. Hematology - HIV, hepatitis B and C tests
9. Biochemistry
10. Urinalysis

11. Urine cotinine test
12. Urine pregnancy test
13. Urine drug screen

Completion date
15/03/2012

Eligibility

Key inclusion criteria
1. Male and female participants
2. Non-smokers
3. Aged between 18 and 55 years of age
4. BMI between 18.5 and < 30.0
5. Healthy as defined by:
5.1. The absence of clinically significant illness and surgery within 4 weeks prior to dosing. Subjects vomiting within 24 hours pre-dose will be carefully evaluated for upcoming illness /disease. Inclusion pre-dosing is at the discretion of the Qualified Investigator.
5.2. The absence of clinically significant history of neurological, endocrinal, cardiovascular, pulmonary, hematological, immunologic, psychiatric, gastrointestinal, renal, hepatic, and metabolic disease.
6. Females of childbearing potential who are sexually active must be willing to use one of the following acceptable contraceptive method throughout the study and for 30 days after:
6.1. Intra-uterine contraceptive device placed at least 4 weeks prior to study drug administration
6.2. Condom or diaphragm and spermicide starting at least 14 days prior to study drug administration
6.3. Hormonal contraceptives starting at least 4 weeks prior to study drug administration and must agree to use the same hormonal contraceptive throughout the study
6.4. Sterile male partner (vasectomized since at least 6 months)
7. Capable of consent

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit
55 Years

Sex
All

Total final enrolment

0

Key exclusion criteria
1. Any clinically significant abnormality or abnormal laboratory test results found during medical screening or positive test for hepatitis B, hepatitis C, or HIV found during medical screening
2. Positive urine drug screen or urine cotinine test at screening
3. History of allergic reactions to donepezil, piperidine derivates, dimenhydrinate or derivatives, or other related drugs
4. Use of any drugs known to induce or inhibit CYP 2D6 or CYP 3A4 within 30 days prior to administration of the study medication
5. Positive pregnancy test at screening
6. Any reason which, in the opinion of the Medical Sub-Investigator, would prevent the subject from participating in the study
7. Clinically significant ECG abnormalities or vital sign abnormalities (systolic blood pressure lower than 90 or over 140 mmHg, diastolic blood pressure lower than 50 or over 90 mmHg, or heart rate less than 50 or over 100 bpm) at screening
8. History of significant alcohol abuse within one year prior to screening or regular use of alcohol within six months prior to the screening visit (more than fourteen units of alcohol per week [1 Unit = 150 mL of wine, 360 mL of beer, or 45 mL of 40% alcohol])
9. History of significant drug abuse within one year prior to screening or use of soft drugs (such as marijuana) within 3 months prior to the screening visit or hard drugs (such as cocaine, phencyclidine [PCP], and crack) within 1 year prior to screening
10. Use of an investigational drug within 30 days (90 days for biologics) or participation in an investigational study within 30 days prior to dosing
11. Use of medication other than topical products without significant systemic absorption and hormonal contraceptives:
11.1. Prescription medication within 14 days prior to the first dosing
11.2. Over-the-counter products including natural health products (e.g. food supplements and herbal supplements) within 7 days prior to the first dosing, with the exception of the occasional use of acetaminophen (up to 2g daily)
11.3. A depot injection or an implant of any drug (other than hormonal contraceptives) within 3 months prior to the first dosing
12. Donation of plasma within 7 days prior to dosing. Donation or loss of blood (excluding volume drawn at screening) of 50 mL to 499 mL of blood within 30 days, or more than 499 mL within 56 days prior to dosing
13. Hemoglobin <128 g/L (males) and <115 g/L (females) and hematocrit <0.37 L/L (males) and <0.32 L/L (females) at screening
14. Breast-feeding subject
15. Presence of tongue piercing or braces at the time of dosing
16. Clinically significant abnormal laboratory values at screening. Note: Eosinophils, Neutrophils and Lymphocytes values must not go over 1.5 times the upper limit of normal.

Date of first enrolment
01/02/2012

Date of final enrolment
15/03/2012

Locations

Countries of recruitment

Canada

Study participating centre
Pharmanet
-
Quèbec
Canada
G1P 0A2

Sponsor information

Organisation
Alkemira SA

ROR
https://ror.org/05c2q0q08

Funder(s)

Funder type
Industry

Funder Name
Alkemira SA

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration