ISRCTN45336965 https://doi.org/10.1186/ISRCTN45336965

A study in healthy subjects to explore the blood levels of a drug when released from the IntelliCap capsule as compared to a marketed drug capsule

Submission date
11/02/2014

Registration date
25/02/2014

Last Edited
21/07/2015

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Other

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
The IntelliCap capsule is a swallowable, electronic, capsule-shaped device. It holds a liquid drug payload. The capsule contains sensors (for acidity and temperature), a battery, a microprocessor, a small motor, and electronics for wireless, real-time communication with an external receiver. When swallowed, it travels through the gut with its natural movement and is excreted with a bowel movement. Real-time data from its sensors are used to locate the capsule within the gut. Upon command, the capsule releases its liquid drug payload in a controlled way over time by the action of a small motor. The study aims to explore the levels of this marker drug in blood when released from the IntelliCap capsule in a pre-programmed way over time compared to a marketed drug capsule.

Who can participate?
Adult men who are healthy as determined by an upfront health check, can participate in the study.

What does the study involve?
Participants are asked to swallow one IntelliCap capsule and a marketed drug capsule in a random order with an interval of one week in between. Blood samples are taken over time to find out the levels of the drug. They have to stay at the clinic each time for about 2 days. Additional assessments are made to monitor safety. After completion, participants have to return to the clinic for a final assessment. Those swallowing an IntelliCap capsule have to wear a mobile phone-size device around their waist that communicates between the IntelliCap capsule in the body and a computer. They have to collect their stool and recover the excreted IntelliCap capsule that is then returned to the clinic.

What are the possible benefits and risks of participating?
No particular benefit is expected or intended for participants. Drug-related risks include swelling of ankles, decrease in the blood pressure, slow heartbeat, upset stomach, dizziness, facial

flushing, headache, light-headedness, skin irritation (rash), tiredness and weakness. Capsule may get stuck in the bowels or the capsule may come apart and could injure the bowels.

Where is the study run from?
ProMedica Clinical Research Center, Brighton, USA.

When is the study starting and how long is it expected to run for?
Recruitment of healthy volunteers for this study started in December 2011 and the study ended in January 2012.

Who is funding the study?
Medimetrics Personalized Drug Delivery Inc., USA.

Who is the main contact?
Dr Christoph Wanke
christoph.wanke@medimetrics.com

Contact information

Type(s)
Scientific

Contact name
Dr Christoph Wanke

Contact details
HighTech Campus 5-2.041
Eindhoven
Netherlands
5656 AE

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
iPS-110077

Study information

Scientific Title
An open-label, randomized, two-period crossover study to explore the pharmacokinetics of diltiazem solution released from the IntelliCap as compared to a marketed diltiazem 60 mg extended release capsule in healthy volunteers

Study objectives

The aim of the study is to explore the pharmacokinetics in healthy volunteers of diltiazem when released as a solution from the IntelliCap capsule with a defined release profile as compared to a marketed extended release capsule.

Ethics approval required
Old ethics approval format

Ethics approval(s)
New England Institutional Review Board, 23/11/2011, IRB# 11-361

Study design
Randomized open-label two-period crossover study

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Pharmaceutical research and development

Interventions
14 male, healthy volunteers at a single site will undergo both of the following interventions in a randomized order with a wash-out period in between of at least 7 days:

1. IntelliCap capsule: payload diltiazem HCl aqueous solution (270 mg/mL), programmed to dispense 60 mg over 24 hours with a first order release profile
2. Diltiazem Hydrochloride Extended-Release capsules USP (60 mg, Cardizem SR®, Mylan Pharmaceuticals Inc., Morgantown, WV 26505, USA)

Subjects have to stay at the clinical center each time for about 2 days. After completion of the treatments, subjects have to return to the clinical center for a final assessment.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)

Diltiazem

Primary outcome measure
Pharmacokinetics of diltiazem released from the IntelliCap as compared to a marketed extended release capsule (AUClast, AUC0-t, AUC∞, Cmax, Tmax, Tlag, T1/2). Blood collection for diltiazem (parent) bioanalysis: pre-administration, 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 16, 24, 36, 48 h post-administration. Diltiazem is determined in plasma by a validated liquid chromatography tandem mass spectrometry (LC-MS/MS) method, lower limit of quantification (LLOQ) at 0.2 ng/mL using 200 µL plasma.

Secondary outcome measures
1. Adverse events, adverse device effects (number, severity)
2. Physical examination: Day -1 in each period, end of study visit (> 4 days after last administration)
3. Vital signs and body measurements: body weight, oral body temperature: Day -1 in each period, end of study visit. Systolic and diastolic blood pressure and pulse rate: Day -1, pre-administration, 1, 2, 3, 4, 5, 6, 8, 10, 12, 24, 36, 48 h post-administration, end of study visit (> 4 days after last administration)
4. ECG evaluation: Day -1 in each period, end of study visit (> 4 days after last administration)
5. Standard clinical laboratory evaluation (hematology: hemoglobin, hematocrit, WBC count with differential (monocytes, eosinophils, basophils, neutrophils, lymphocytes) as absolute value, RBC count and platelet count. Blood chemistry: albumin, alkaline phosphatase, bilirubin (total, direct and indirect), bicarbonate/CO2, calcium, cholesterol, chloride, creatinine, CK, gamma-GT, glucose, LDH, inorganic phosphorus, lipase, amylase, magnesium, potassium, total protein, AST, ALT, sodium, triglycerides, urea/BUN and uric acid. Urinalysis: specific gravity, pH; semi-quantitative 'dipstick' evaluation of glucose, protein, bilirubin, ketones, leukocytes, blood): Day -1 in each period, 24 h post-administration, end of study visit (> 4 days after last administration)

Overall study start date
27/12/2011

Completion date
23/01/2012

Eligibility

Key inclusion criteria
1. Provision of informed consent
2. Healthy male subjects age 18 to 45 years of age inclusive
3. Vital signs: body temperature between 35.0 and 37.5 °C, systolic blood pressure 90-140 mmHg, diastolic blood pressure 60-90 mmHg, pulse rate 50-90 bpm
4. Body weight > 50 kg, BMI 18 to 29 kg/m2

Participant type(s)
Patient

Age group
Adult

Lower age limit

18 Years

Sex
Male

Target number of participants
14

Key exclusion criteria
1. Smoking
2. Use of prescription drugs, herbal supplements, over the counter medication
3. Significant ECG (electrocardiogram) abnormalities
4. Surgical or medical condition which might significantly alter the absorption, distribution, metabolism or excretion of drugs
5. Impaired renal function
6. Pacemakers or other implanted electro-medical devices
7. Swallowing disorder
8. Scheduled MRI assessment

Date of first enrolment
27/12/2011

Date of final enrolment
23/01/2012

Locations

Countries of recruitment
Netherlands

United States of America

Study participating centre
HighTech Campus 5-2.041
Eindhoven
Netherlands
5656 AE

Sponsor information

Organisation
Medimetrics Personalized Drug Delivery B.V. (Netherlands)

Sponsor details

c/o Christoph Wanke
HighTech Campus 5-2.041
Eindhoven
Netherlands
5656 AE

Sponsor type
Industry

Website
http://www.medimetrics.com

Funder(s)

Funder type
Industry

Funder Name
Medimetrics Personalized Drug Delivery Inc. (USA)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/12/2014		Yes	No