An open-label, phase 1 study in healthy elderly females to investigate the pharmacokinetic profile of a fixed combination of 25 mg nandrolone decanoate and 14.000 IU vitamin D3 (ON 001) administered subcutaneously.

Published: 05-09-2012
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To investigate the pharmacokinetic profile of a single dose of ON 001 administered subcutaneously.To examine the safety and tolerability of a single dose of subcutaneously administered ON 001.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bone and joint injuries
Study type	Interventional

Summary

ID

NL-OMON37203

Source
ToetsingOnline

Brief title
ON 001.01

Condition

- Bone and joint injuries

Synonym
Recovery from hip fractures

Research involving

Human

Sponsors and support

Primary sponsor: OrgaNext Research B.V.
Source(s) of monetary or material Support: OrgaNext Research BV.

Intervention

Keyword: Healthy elderly women, Pharmacokinetics, Safety, Tolerability

Outcome measures

Primary outcome

Pharmacokinetics

Secondary outcome

safety and tolerability

Study description

Background summary

The research medication is a medication under development for the rehabilitation after hipfractures.

Study objective

To investigate the pharmacokinetic profile of a single dose of ON 001 administered subcutaneously.

To examine the safety and tolerability of a single dose of subcutaneously administered ON 001.

Study design

single centre, single dose, open label, phase 1

Intervention

The study will start with a screening. At the screening a physical examination will take place and a few other standard medical assessments will be performed

(Vital Signs; ECG). Furthermore a blood and urine sample will be taken for laboratory tests and an alcohol breath test and drug screen will be done. During the stay in the clinic the subject will receive the study medication and on several time points blood will be taken and urine will be collected. The subjects will be asked for possible side effects on a regular basis. Furthermore several safety assessments will be done frequently.

Finally a follow up vist will take place and an end of study phone call.

Study burden and risks

ON 001 has not previously been tested in humans. Nevertheless, both components of the research medication are commercially available and both are generally well tolerated, in doses higher than in the present study. Studies have shown that Vitamine B3 is well tolerated in doses up to 600.000 IU and studies using doses of 50 mg of Nandrolone decanoate have also shown that this dose was generally well tolerated.
The dose has been selected on a level, where risks are considered to be minimal, but unforeseeable side effects could occur. The most important side effects in studies where 50 mg Nandrolone decanoate was administered is were hoarseness and weakness of the voice.

The blood collection may cause discomfort or bruising. Occasionally, fainting, an infection at the blood sampling site, bleeding and blood clot formation can occur.

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

- Caucasian females with a minimum age of 65 years and a maximum age of 80 years and a BMI between 20 and 30 kg/m2.;- Good physical and mental health. No clinical relevant findings as determined by the Principal Invesigator based on the past medical history, physical examination, vital signs, 12-lead ECG and clinical laboratory test results at screening and baseline.;- Subjects* clinical laboratory tests must be within normal limits or clinically acceptable to the investigator at screening. ;- The 12-lead ECG conduction intervals must be within female-specific normal range (QTcB <= 450 msec, PR interval <= 200 msec).;Refer to protocol for a complete list of inclusion criteria

Exclusion criteria

- Treatment with another investigational drug within 4 months prior to dosing.;- Donation or loss of 500 mL or more of blood within 90 days prior to administration of the study medication.;- Positive urine drug screen or alcohol breath test.;- Serology positive for hepatitis B, hepatitis C, or HIV antibodies.;- History of sensitivity to nandrolone decanoate, vitamin D3 or chemically related compounds or excipients.;Refer to protocol for a complete list of exclusion criteria

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):	18-09-2012
Enrollment:	14
Type:	Actual

Ethics review

Approved WMO Date:	05-09-2012
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

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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	EUCTR2012-000977-21-NL
CCMO	NL41852.056.12